GORDON COMMISSION REPORT:

the pricing of multiple-source drug products in Ontario

presented to

The Honourable Keith Norton
Minister of Health
Province of Ontario

August 1984

REPORT OF THE COMMISSION ON THE PRICING OF MULTIPLE-SOURCE DRUG PRODUCTS IN ONTARIO

Dean J.R.M. Gordon
Commissioner
August 1984

SCHOOL OF BUSINESS

Queen's University
Kingston, Canada
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August 31, 1984

Honourable Keith Norton, M.P.P.
Minister of Health,
Government of Ontario.

Dear Mr. Norton:

I am pleased to present the Gordon Commission Report on the Pricing of Multiple-Source Drug Products. As directed, I have addressed the areas of concern specified in the Terms of Reference, and I have included in my report recommendations for resolving the problems so identified.

I wish to thank you for giving me this opportunity to contribute to the well-being of Ontario's health care programmes. I would be more than pleased to meet with you at your convenience to discuss my recommendations.

Yours sincerely,

Dean J.R.M. Gordon,
Commissioner.

JRMG;ms
Encl.

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EXECUTIVE SUMMARY

The Gordon Commission was established in March 1984 by the Ministry of Health, the Ontario Pharmacists' Association, the Canadian Drug Manufacturers Association, and the Pharmaceutical Manufacturers Association of Canada to make recommendations regarding several areas of concern which have become increasingly critical over the past few years. These problems, as defined in the Commission's Terms of Reference, are:

1. the basis for determining the prices listed in the PARCOST C.D.I./Drug Benefit Formulary for multiple-source drug products;

2. the relationship between the negotiated dispensing fee and drug cost reimbursement, and whether the former should be adjusted when the basis for determining the latter is changed;

3. the need, if any, for amendments to the legislation governing the selection and substitution of interchangeable drug products, Section 155 of the Health Disciplines Act.

The Commission presented its report to the four principal parties on August 31, 1984, and the following summary provides the highlights of the report.

The report begins with an introduction which provides a general description of health care policy issues. This is followed by a section which describes the establishment of the Commission and lists the individuals and organisations from whom the Commission received information and proposals concerning the problems identified in the Terms of Reference.

The next section of the report summarises the Commission's interpretation of the Terms of Reference. This interpretation extends beyond the specific issues identified in the Terms of Reference to include

the impact of these issues on the operation of the entire Ontario retail prescription market. The Commission supports this broad interpretation by pointing out the strong interrelationships which exist among the various policies and programmes now in place, and between the Drug Benefit and non-Drug Benefit segments of the market. Because of these interrelationships, changes to one programme affect others, and events in one market segment influence the other.

The fourth section of the report begins with a brief review of federal and Ontario regulatory actions with respect to prescription drugs from 1969 to the present. These two levels of policy are presented by the Commission as being complementary; the promotion of interchangeability, for example, depends on federal legislation for its existence, and the provision of price and quality information is an extension of federal endeavours.

The remainder of the fourth section includes the bulk of the analysis of Ontario's current programmes and policies. This analysis is presented in two sections--the first examines the main structural elements of these programmes, and the second examines the effectiveness of the programmes and the views of the four principal parties on the problems being encountered and on the most appropriate solutions for these problems.

The first section of this analysis focuses on the PARCOST C.D.I./Drug Benefit Formulary and the prices listed therein, the negotiated dispensing fee, and product selection and substitution, and analyses them with respect to their intended effects and their actual operation. The main conclusion of this analysis is that while these elements fulfill in most instances the roles intended for them, they are also used for purposes beyond, and

sometimes contrary to, these stated intentions. For example, the prices listed in the Index/Formulary are used, as intended, as the reimbursement prices for pharmacies dispensing Drug Benefit prescriptions; they are also used, however, by some manufacturers to practice spread-pricing, a marketing strategy which depends on inflated prices being listed in the Index/Formulary.

The negotiated dispensing fee is used, as intended, as a means of reimbursing pharmacies for the professional services they provide to Drug Benefit recipients; it is also used, however, as a negotiating tool by pharmacists in a variety of ways. And, finally, Section 155 is seen as only fulfilling its purpose of controlling prescription prices when it is reinforced by mandatory price substitution in the Drug Benefit market.

The second section focuses on Ontario's programmes and policies--PARCOST, Drug Benefit, and Section 155, and analyses whether they achieve their objectives or not. The Commission concludes that, while most of their objectives are met, these programmes are thwarted in their attempt to control prescription prices primarily because of the practice of spread-pricing. This section of the report also notes that, in their presentations to the Commission, all four principal parties deplore the use of spread-pricing, and, although their proposed solutions differ significantly, they all call for a return to realistic drug reimbursement prices. Following a review of the positions taken by the four principal parties, this section concludes by discussing the availability of information throughout the retail prescription market, the uses to which

that information is put, and the potential for creating more cost controlling competitive behaviour through greater consumer awareness at various stages in the drug distribution process.

The next section of the report provides an overview of the options available to the Ministry of Health by describing, among others, a system more strongly driven by the marketplace (British Columbia Pharmacare), and a system more directly regulated (Saskatchewan Prescription Drug Plan). The report emphasises that no system is fault-free, and that a requisite for the smooth functioning of any system is the co-operation of all parties involved.

Finally, the report puts forward two sets of recommendations. The primary recommendations speak to the issues identified in the Terms of Reference and are:

PRICES

1. the Index/Formulary should continue to list prices for each drug product in an interchangeable group, and the price listed should be no more than 20% higher than the best volume price available from the manufacturer for the package size listed;

2. manufacturers should sign agreements guaranteeing that all price information submitted is accurate and will be adhered to;

3. the list of high-volume drug products should be revised regularly.

4. prices listed should be revised quarterly;

DISPENSING FEE

1. the Ministry of Health and the Ontario Pharmacists' Association should continue to negotiate a single dispensing fee, and should collect objective dispensary cost information to assist in their negotiations;

2. the dispensing fee should not be adjusted when the basis for determining prices for listing is changed, and the $0.35 fee adjustment should be included in the base for fee negotiations.

SECTION 155

1. pharmacies should be allowed to charge a usual and customary fee on product selected and substituted prescriptions;

2. the price charged for product substitution prescriptions should only be restricted to being less than the price that would be charged for the drug prescribed;

3. a target level of substitution should be established, and progress toward that goal should be monitored.

The secondary recommendations address more general concerns identified by the Commission, and are:

1. the Ministry of Health should monitor the retail prescription market more extensively;

2. an independent research firm should be commissioned to conduct a continuous consumer panel on health services in Ontario;

3. pharmacies should post their dispensing fees, and include drug cost and dispensing fee information on prescription labels;

4. Drug Benefit should be restructured to include either a recipient co-payment, only partial reimbursement beyond a deductible level of payment, or full reimbursement to the recipient;

5. pharmacy organisations should inform the public of the professional health care services available from pharmacists;

6. the interim payment method of reimbursing pharmacies should be eliminated;

7. the Ministry of Health should use its dominance in the market more forcefully, and should develop a better working relationship with pharmaceutical manufacturers;

8. the Ministry of Health should work with pharmacy and

physician organisations to reduce waste of prescription drugs, and to increase public awareness of the impact of lifestyle on health;

9. a "dispense as written" policy should be instituted for Ontario Drug Benefit;

10. the Ontario Medical Association should educate its members about the benefits of prescribing generically and of prescribing lower-cost products from generic manufacturers.

I. INTRODUCTION

Whenever any aspect of a health care system is studied as Ontario Drug Benefit has been over the past six months, those conducting the study must necessarily become familiar with the way in which the aspect under consideration fits into the entire health care system. During the past six months, my staff and I have learned a considerable amount about health care services, their delivery and administration. By way of introduction to this Report, we would like to outline briefly our view of the public policy issues in health care which relate to Ontario Drug Benefit.

For any government in Canada, health care policy no longer begins with the question of whether or not there should be public involvement in the delivery and funding of health services. Universally accessible, quality health care is now firmly entrenched as a government responsibility. Health care policy begins, rather, with two main questions. First, of the resources available, how many should be devoted to health care? Second, how should the resources devoted to health care be allocated so that the services available are of the best kind and quality and are of reasonable cost?

With respect to the first question, governments must decide what proportion of resources available should be directed toward health care and not toward other public activities, such as education, industrial development, or agriculture? These areas of spending are only apparently unrelated--many studies have shown, for example, that a person's length of schooling and his or her health are strongly correlated.[22] Or,

conversely, in the area of industrial development, it is clear that a reliance on drug therapy brings with it a flourishing pharmaceutical industry. In addition, a growing economy is likely to enhance the ability of either a government or its citizens to increase their quality of life, at least partly through an increased ability to fund better health services.

Any government's decision on these questions will depend to some extent on its perception of the factors in society which contribute to improving its citizens' health, and its perception of the best way of influencing those factors. As well, the decision would depend on short-term vs. long-term considerations. Thus, for example, funds spent on pollution control or on industrial health and safety may have a significant and long-lasting impact on the health of citizens in the future. On the other hand, immediate health problems require immediate attention, and it is difficult to redirect funds from present therapeutic programmes to more indirect preventative programmes.

With respect to the second question, governments must decide which health services to fund and how to fund them. In answering this question, governments must consider the relative effectiveness of different therapies and how the funding can be structured to promote efficiency in the delivery of services. This is a most difficult task. In the area of prescription drugs, for example, it can be argued that, in some cases, the use of these potent medications reduces the need for other, more costly, health services; as well, it can be argued that increasing the ability of citizens to self-medicate by making more prescription drugs available as

over-the-counter products would be effective in reducing demand for the services offered by health care professionals. On the other hand, it can be argued that behaviour modification programmes, such as anti-smoking campaigns and programmes to raise public awareness about fetal alcohol syndrome, would lower the usage of health services overall.

Turning to the delivery of health services, governments must consider whether to operate the delivery system themselves, through government-owned hospitals and clinics, for example, or whether to pay private service providers, individual and institutional, for health care services. In either case, the government is regulating the delivery of health care services; in the latter case it is doing so by regulating the activities of private individuals and institutions. In this case, it must determine which of a variety of funding and reimbursement mechanisms will best achieve the delivery of appropriate services to those who need them, and provide adequate remuneration to service providers.

If a government chooses this latter approach, as the Ontario government has with respect to prescription services, it can only do so with the co-operation of service providers. Their co-operation is needed not only to operate the programme, but also to ensure it is not abused, and to help resolve any problems which may arise. In other words, the effective delivery of services requires the co-operation of all parties involved despite differences in their outlook and objectives. Respect for the role of other participants, and a willingness to work toward a system which accomplishes its goals in a way mutually beneficial to all is a basic requirement of any such system. Equally fundamental on the part of all

participants is a recognition that the dominant concern in health delivery must be for the consumer. The consumer's physical and mental health, and her or his ability to pay are the paramount considerations which must be satisfied at all times.

In examining Ontario Drug Benefit, the Commission has detected, on some matters, a lack of co-operation and concern for consumers on the part of those involved in the programme. No specific recommendations can change this; rather, the Commission can only encourage manufacturers, wholesalers, physicians, pharmacists, and public officials to seek out areas of mutual agreement and to work together toward a system which serves the public interest. The participants in this system must realise that their co-operation is essential to the success of any prescription drug programme. The functions performed by each participant are essential to its well-being: without the innovative approach to drug therapy of the patent-holding manufacturers, the cost competition provided by the generic manufacturers, the efficient distribution network of the wholesalers, the concern for public health of pharmacists and physicians, and the political will and financial resources of the Ministry of Health, the system would simply not work. Thus, the potential rewards of co-operation far exceed the effort demanded of each participant.

The Commission's main task has been to make recommendations about specific structural elements of current government policies and programmes. These recommendations have been made within the framework of the public policy issues just discussed, and have been divided into two categories--primary and secondary. The primary recommendations address

the specific problems defined by the Commission's Terms of Reference; the secondary recommendations address more general issues and have been made, in part, in response to concerns expressed by some of the system's participants, and, in part, to identify certain issues believed by the Commission to merit attention.

The following Report includes a description and analysis of Ontario's current public policies and programmes respecting prescription drug services, and recommendations to improve the operation of these policies and programmes. The Commission hopes that these recommendations will help all participants to understand the market of which they are an integral part and to improve the delivery of prescription services in Ontario.

II. DESCRIPTION OF THE COMMISSION

On March 1, 1984 the Ontario government, by Order-in-Council, appointed Dean John R. M. Gordon of the School of Business, Queen's University as a Commissioner to study the pricing of multiple-source products in the PARCOST C.D.I./Ontario Drug Benefit Formulary and report his findings to the Minister of Health. This appointment was made under Section 9 of the Ministry of Health Act, and was the result of an agreement between four principal parties—the Honourable Keith Norton, Minister of Health; the Ontario Pharmacists' Association; the Canadian Drug Manufacturers Association; and the Pharmaceutical Manufacturers' Association of Canada—that an independent study into this and related matters was needed to determine, in general, how the operation of Ontario Drug Benefit could be improved so that none of the major participants in the programme suffer undue hardships or reap undue benefits from it.

The four principal parties also agreed upon the framework within which the Commissioner was to operate. Specifically, they agreed to three Terms of Reference, to August 31, 1984 as the date of completion, and to limiting the initial distribution of the final report to themselves. Within this framework, the Commissioner was to act at arm's length from all four parties, to gather all the information he required, and to expect and receive the full co-operation of the four principal parties. In the view of the Commissioner, this framework has been successful in allowing an independent appraisal of the current situation, and in leading to recommendations which will improve the effectiveness of the programme, and

the relationships among the principal parties.

The work of the Commission proceeded through three stages. The first stage, from March to June, consisted primarily of gathering information about the retail prescription market in Ontario, and about the operation of public and private third-party reimbursement plans and programmes in Ontario and elsewhere in Canada. The second stage, in July, included informal meetings between the Commissioner, his staff, and each of the four principal parties, as well as with Green Shield Prepaid Services, Inc. The third stage, which occupied the latter part of July and the month of August, focused on careful analysis of the information and recommendations received from all parties, and the preparation of this report.

The following list of the people and organisations with whom the Commission met over the past six months is intended to provide an overview of the range of sources on which the Commission relied for information. Those marked with an asterisk presented submissions to the Commission.

Pharmacy

*Ontario Pharmacists' Association
*Ontario College of Pharmacists
*Metropolitan Toronto Pharmacists' Association
*Society of Independent Community Pharmacists of Ontario
Ottawa Civic Hospital
Head of Pharmacology, Queen's University
Kingston General Hospital

Manufacturers

*Canadian Drug Manufacturers Association
*Pharmaceutical Manufacturers' Association of Canada
*Frank W. Horner Inc.
Johnson & Johnson, Inc.
Novopharm Ltd.

Parke Davis Canada Inc.
Apotex Inc.

Private Third-Party Payers

*Canada Life and Health Insurance Association
*Green Shield Prepaid Services Inc.
*Ontario Hospital Association (Blue Cross)

Provincial Governments

British Columbia: Mr. P. Tidball, Manager, Pharmacare
Alberta: : Mr. Bougher, Pharmacy Consultant, Ministry of Hospitals and Medical Care
Saskatchewan: : Mr. R. Waschuk, Executive Director, Saskatchewan Prescription Drug Plan
Dr. L. Strand, Director of Program Evaluation, SPDP
Mr. T. Quinn, Director of Formulary and Education, SPDP
Manitoba : Mr. K. Brown, Pharmaceutical Consultant, Manitoba Health Services Commission
Quebec : M.P. Boucher, Adjoint Executif au President-directeur general, Regie de l'assurance-maladie du Quebec
M.P. Guertin, Head, Drug Reimbursement Division, Regie de l'assurance maladie du Quebec
Nova Scotia : Mr. J. Hare, Executive Director, Nova Scotia Health Services and Insurance Commission
Ontario : *Honourable Keith Norton, Minister of Health
Mr. Gerard Raymond, Deputy Minister of Health
Mr. D. Kealey, Assistant Deputy Minister, Community Liaison and Corporate Resources
Mr. R. LeNeveu, Assistant Deputy Minister, Administration and Health Insurance
Dr. A. Dyer, Associate Deputy Minister, Institutional Health
Dr. W. Mahon, Chairman, Drug Quality and Therapeutics Committee
Mr. A. Burrows, Acting Director, Drug Programs and Policy Group
Mr. H.I. MacKillop, Director, Data Development and Evaluation Branch

Government of Canada

Consumer and Corporate Affairs: Mr. T. Brogan, Policy Analyst
Mr. L. Hunter, Assistant Deputy Minister, Bureau of Competition Policy
Mr. D. Watters, Director, Policy Analysis and Liai

National Health and Welfare: Mr. K. Commons, Pharmacy Market Adviser
Dr. E. Napke, Chief, Product Related Disease Divis Bureau of Epidemiology
Mr. B. Rowsell, Director, Drug Quality Assurance Program

Supply and Service Canada: Mr. R. Kennett, Drug Adviser, Consumer Products and Traffic Management Branch

Department of Regional Industrial Expansion: Mr. G. Pineault, Commerce Officer, Service Industries Branch

United Kingdom

Mr. L. Wilson, Administrator for Pharmaceutical Services, Department of Health and Social Security

France

Dr. C. Woler, Marketing Director, Laboratories RETI
Professor B. Chaput, University of Clermont-Ferrand

Other

*Consumers' Association of Canada
*Drug Trading Company Limited
*Ontario Medical Association
Mr. D. Forbes, Past President, Drug Trading Company Limited
Dean R. Fraser, Director of Research, Eastman Commission
Ms. A. Masson, Bureau of Economics, Federal Trade Commission, Washington
Dr. H. Segal, Professor, Faculty of Pharmacy, University of Toronto
Faculty of Law, Queen's University,
Intercontinental Medical Statistics Canada

From the foregoing, it should be clear that the Commission recognised that the matters being studied affected, and were affected by, not only the four principal parties, but also other pharmacists and manufacturers not represented by O.P.A., C.D.M.A., and P.M.A.C., and reimbursement plans other than Ontario Drug Benefit. Thus, to gain a clear understanding of the issues before it, the Commission solicited the views of several groups and organisations beyond the four sponsoring parties. Further, the Commission did not ignore previous work that had been done in this area--the 1971 Porter Report on product substitution, and the 1978 Bailey Report were fundamental to understanding the development of the matters being reviewed, as were a wide variety of less formal documents, such as correspondence and unpublished studies, supplied by various participants.

As well, the Commission had the benefit of a study done by Woods Gordon Consultants on behalf of the O.P.A. on recent trends in the operating margins and profits of Ontario pharmacies.

The Commission also established contact with other provincial governments, several federal government departments, and with some European countries to learn, generally, about their approach to drug prices, and, specifically, about their drug reimbursement programmes. Overall, therefore, the Commission believes it has gained a comprehensive understanding of both the business and policy aspects of the matters under review, and of the mechanisms by which various jurisdications seek to achieve the same policy objectives.

The Commissioner would like to thank the organisations which participated in this study, all of which were very co-operative and showed not only a strong desire to assist the Commission in any way possible, but also a commitment to arrive at constructive solutions to the problems which gave rise to this review in the first place. This attitude, shared more or less equally by all participants, has done much to make the Commission's work easy. The Commissioner hopes that his efforts, and those of his staff, have been equal to the task at hand, and that this report is sufficient to satisfy the mandate of the Commission.

Finally, the Commissioner would like to thank his staff for their assistance. They were responsible for much of the day-to-day liaison with all participants, the research, and the coordination of the not inconsiderable amount of information gathered over the past six months. Without their help, the Commission would have been unable to gather the

amount of information it did, and analyse it as closely as has been done.

III. TERMS OF REFERENCE

The Terms of Reference for the Commission to Review the Pricing of Multiple-Source Products in the PARCOST C.D.I./Ontario Drug Benefit Formulary are as follows:

1. On what bases and by what means should the prices for multiple-source products be determined for the purposes of listing in the PARCOST C.D.I. and the Ontario Drug Benefit Formulary in their present forms or as they may be amended?

2. What adjustment, if any, apart from normal periodic negotiated fee increases, should be made in the dispensing fee provided for in relation to the PARCOST C.D.I. and the Ontario Drug Benefit Formulary as a consequence of implementing the answer to Question 1?

3. Should there be any changes in the provision regarding product selection under Section 155 of the Health Disciplines Act?

Thus, the Commission was directed to study what are acknowledged to be the cornerstones of both the PARCOST programme and Ontario Drug Benefit--the Formulary, the drug prices listed therein for multiple-source products, the interrelationship between the drug cost reimbursement and the dispensing fee paid by the Ministry of Health to pharmacists for performing professional services for programme beneficiaries, and the legislation concerning product selection and substitution.

These Terms of Reference are quite specific in the issues they raise, and focus on the problem of the pricing of multiple-source products, on determining how pharmacists should be compensated for their services, and whether product substitution is being encouraged in both the private and public prescription markets. These issues do not, of course, exist in

isolation. They are connected with events that have taken place over the past fifteen years in the Canadian pharmaceutical industry, and, more importantly, with the evolution of provincial programmes, beginning with PARCOST in 1970, that have been directed at controlling the cost of prescription drugs.

Thus, with respect to the Terms of Reference, the Commission has found it necessary to go beyond a strict interpretation and to examine the issues they raise in the context of the nature and operation of the retail prescription market in Ontario, the federal regulatory environment for the pharmaceutical industry created by Section 41(4) of the Patent Act, and the structure of, and relationship between, private and public drug reimbursement programmes. In short, the issues raised by the Terms of Reference can be viewed as lynch-pins: their impact goes beyond the provincial programmes with which they are most directly associated to have a direct effect on all the participants in the prescription market from manufacturers to wholesalers, from doctors to pharmacists, and from government to its citizens.

The following brief description of the Terms of Reference summarises the issues identified by each, and the implications thereof. No analysis of these issues is presented in this section; rather, it is intended to make the Commission's understanding of the Terms of Reference clear from the start, and to state the basis on which the remainder of the report can best be understood.

TERM OF REFERENCE 1:
PRICING OF MULTIPLE-SOURCE PRODUCTS

The PARCOST C.D.I./Drug Benefit Formulary provides three types of information: the drug products which are provided free of charge to Ontario Drug Benefit recipients; the products which have been certified as interchangeable by the Ministry of Health; and the prices of all listed products. The Index/Formulary, therefore, serves as a guide to doctors for prescribing purposes, to pharmacists for purchasing and dispensing decisions, to manufacturers for pricing and marketing activities, and to private and public payers for reimbursement levels.

The principal issue raised by this Term of Reference is that of spread-pricing. The price listed in the Index/Formulary for any product is intended to be that which would be paid by the average pharmacy for one package of 100 tablets or capsules. It is alleged, however, that some manufacturers, primarily for marketing purposes, submit prices for listing in the Index/Formulary which exceed this price to a greater or lesser degree.

The implications of this are wideranging: market advantages, not based on product quality or true prices, may accrue to manufacturers practising spread-pricing; third-party payers, whether public or private, often base their drug cost reimbursement to pharmacies on the Index/Formulary price and may, therefore, be paying more than necessary for drug products; pharmacists may charge cash customers drug costs based on the Index/Formulary price, and may, therefore, be receiving reimbursement in excess of that which is deemed appropriate by pharmacists and third-party payers alike; the goal of containing drug costs is not being achieved in

every instance; and, finally, the delivery of provincial programmes may not be able to withstand public scrutiny.

The second issue raised by this Term of Reference is the role of the Index/Formulary itself. Although formularies are used more often than not by provincial drug reimbursement programmes, they need not be used, or they need not take the form of the PARCOST C.D.I./Drug Benefit Formulary. Since the Index/Formulary serves a number of purposes, such as listing eligible benefits for Ontario Drug Benefit and certifying the interchangeability of certain products, the implications of this issue are also significant as they extend to touch the areas of product substitution and selection and manufacturers' marketing practices, among others.

Thus, in considering this Term of Reference, the Commission believes it necessary to consider the ways in which the Index/Formulary, and the prices listed therein, act as the structural underpinnings of the relationships between participants in the retail prescription market in Ontario, and have a direct and considerable effect on the services offered to customers, the economic well-being of pharmacies, and the effectiveness of public and private drug reimbursement programmes.

TERM OF REFERENCE 2: ADJUSTMENT TO THE DISPENSING FEE

The dispensing fee paid to pharmacists can best be understood as part of the "cost plus fee" concept of pharmacy reimbursement which was developed by Professor H. J. Fuller, Faculty of Pharmacy, University of Toronto in the early 1960s. Under this concept, which is now widely used, reimbursement to pharmacists for filling a prescription is based on the cost of the drug product dispensed and a professional fee intended to cover

all variable and fixed operating costs and to provide a reasonable profit. For Ontario pharmacies, there are essentially two different fees which are applicable to prescriptions depending on, first, who the ultimate payer is, and, second, whether the pharmacist has practised product selection or product substitution when dispensing the drug product prescribed.

The most immediate issue raised by this Term of Reference is whether a change in the basis of determining prices for listing in the Index/Formulary should be accompanied by an adjustment in the negotiated dispensing fee applicable to Drug Benefit prescriptions. In February 1984, the Ministry of Health adjusted this fee by $0.35 when the Index/Formulary prices were lowered for thirty high-volume multiple-source drug products. Prices for these thirty products were changed in one of three ways: the prices of sixteen products already listed in the 1000 package size were adjusted downward; the 100 package size price listing for ten products was also lowered; and the prices for four products were changed from being based on a package size of 100 to being based on a package size of 1000. The fee adjustment was agreed to by the Ministry of Health and the Ontario Pharmacists' Association as a temporary measure pending the completion of this report, and was made without prejudice to the conduct of fee negotiations. In return for this adjustment, the Ontario Pharmacists' Association assisted the Ministry of Health in determining more realistic prices for the thirty drug products. A fee adjustment of $0.22 was made in 1979 when Index/Formulary prices for thirty-six high volume multiple-source drug products were changed to reflect the cost of a package of 1,000 tablets rather than a package of 100 tablets. These adjustments relate to

the fact that under the present system of Drug Benefit reimbursement some portion of a pharmacist's revenue is derived from the difference between what the pharmacist pays for a drug product and what s/he receives as reimbursement. This difference is known as cost/price differential and has two elements--one is purchasing advantage, which arises from the pharmacist purchasing in bulk and thereby paying less than the Index/Formulary price for a drug product; the second is spread, which arises when the Index/Formulary price has been inflated by a manufacturer. Thus, in 1979 and 1984, when the cost/price differential on certain products was decreased, because of price changes, the negotiated dispensing fee was adjusted [Appendix A].

The crux of this issue is, again, spread-pricing. The first question which must be addressed is whether the revenue received by pharmacists through spread-pricing is legitimate, that is to say, accepted by pharmacists and payers alike as an appropriate source of revenue. Is spread revenue viewed in the same way as revenue from purchasing advantage, that is, as a justifiable reward for good business practices? It is in this context that the principle of fee adjustments has been considered by the Commission.

The second, and larger, question to be addressed is the relationship between the two components of pharmacy reimbursement. Turning again to the concept of 'cost plus fee', we must consider the relationship between pharmacy revenue from cost/price differential and from the negotiated Drug Benefit fee, and whether the former has been used to keep the latter at a level lower than would be necessary for the concept of the professional fee

to be fulfilled. Other factors must also be analysed in this context, such as differences in the costs of dispensing caused by the administrative duties associated with third-party reimbursement, and differences in revenue from prescription services attributable to dispensing quantity guidelines.

Overall, then, this Term of Reference speaks to the costs and revenues associated with operating a retail pharmacy, the sources of revenue available to pharmacies, the level of reimbursement required to guarantee an adequate livelihood for pharmacists, and, finally, the ways in which the provincial government's targeted programme influences the operation of the private reimbursement plans and the cash prescription market. The negotiated fee must be analysed with respect to its relationship to the other sources of revenue available to pharmacy including purchasing advantage. If the fee is inadequate, have pharmacies been seeking compensating revenue from other sources such as spread-pricing or a higher marketplace fee? If the fee is adequate, have pharmacies had other reasons for seeking compensating revenue such as extra administrative costs created by third-party plans? And, finally, if pharmacies have secured compensating revenue, on whom has this burden fallen, and on whom should it fall?

TERM OF REFERENCE 3:

SECTION 155

The third Term of Reference refers to that section of the Health Disciplines Act which deals with product selection and substitution, where product selection is the act of dispensing an interchangeable product when

the prescription identifies the product to be dispensed by active ingredient, strength and dosage form only, and product substitution is the act of dispensing an interchangeable drug product when the prescriber identifies the product to be dispensed by brand name, but does not prohibit substitution. Product selection is, of course, mandatory; product substitution is permissive and is done only at the pharmacist's discretion. The bulk of Section 155 speaks to the conditions which must be fulfilled when the pharmacist product selects or substitutes, defines the amount which the pharmacist may charge for a product selected or substituted prescription, and protects pharmacists and prescribers from civil litigation arising from injurious acts caused by product selection or substitution.

The primary issue raised by this Term of Reference is that of reimbursement for product selected and substituted prescriptions dispensed for non-Drug Benefit customers, for it is through Section 155 that the Index/Formulary prices and the negotiated dispensing fee are applied most explicitly to the portion of the retail pharmaceutical market not included in Ontario Drug Benefit. This connection is spelled out in Section 155(3): on a product selected or substituted prescription, the pharmacist may only charge the drug product cost for the least expensive interchangeable product in her or his inventory and the negotiated dispensing fee. If, as has been alleged, the negotiated fee is lower than the marketplace fee, then this constraint on reimbursement can be viewed as a disincentive to product substitute. As a result, the practice of product substitution as a way of lowering prescription prices to private third-party and cash-paying customers has been eroded, and may be failing to achieve its intended

purpose.

The Commission, therefore, in considering this Term of Reference, has had to do so in conjunction with the preceding Term of Reference regarding the dispensing fee. More generally, the Commission has considered what incentives, if any, are necessary to encourage the practice of product substitution, and to what extent, if any, pharmacies should, or should be allowed to, charge differently when exercising product selection and substitution.

Secondary issues which arise from this Term of Reference do so because of the close relationship which exists between Section 155 and the PARCOST C.D.I./Drug Benefit Formulary. These issues include the designation of interchangeable products, the use of the Maximum Allowable Cost to enforce mandatory price selection for Ontario Drug Benefit prescriptions, and the permissive nature of the current legislation. Section 155 is part and parcel of both the PARCOST program and Ontario Drug Benefit; a change in the underlying structure and mechanisms of either, such as the formulary or methods of reimbursement, is likely to require amendments to Section 155.

These, then, are the Terms of Reference set down for the Commission by the four principal parties, and the Commission's interpretation of them. The broad issues which arise from the Terms of Reference relate directly to nearly all segments of the prescription market in Ontario: the determination of appropriate mechanisms of reimbursement to pharmacists, the extent to which public policy should govern the market, and the maintenance of high quality, efficient services throughout the market, from manufacturers to the ultimate payers. In analysing these issues, the

Commission has attempted to devise recommendations which ensure that the market operates effectively, and that the mechanisms employed to carry out public policy regarding pharmacy services are capable of responding to changing conditions, and of treating all participants fairly.

IV. DESCRIPTION AND ANALYSIS OF THE PRESENT SITUATION

A. Background

The retail price of prescriptions, while it is the immediate concern of this Commission, is not a new issue, nor is it isolated to this province or to this country. It is a rare government, among Western nations, which does not take some measures to control prescription prices. In Canada, federal and provincial governments have been most active on this front over the past two decades, and have concentrated their efforts primarily in three areas—providing information on drug prices and quality to prescribers and pharmacists, controlling or influencing manufacturers' selling prices, and relieving certain population groups of the burden of paying for prescription drugs.

The prescription drug programmes currently in place in Ontario gain their force from, and are representative of, these efforts. The following review of the recent history of policy and legislative actions directed at controlling prescription drug prices is intended to provide a framework for analysing Ontario's programmes, and the benefits and problems that arise therefrom.

GOVERNMENT OF CANADA: LEGISLATION AND PROGRAMMES

At the federal level, the three studies of drug prices which were undertaken in the 1960s provided, through their recommendations, the foundation and the general direction for many of the policy actions that

followed. These studies were the Restrictive Trade Practices Commission in 1963, the Royal Commission on Health Services in 1964, and the Special Commission on Drug Costs and Prices in 1967. At the end of this decade of study, the Government of Canada took two actions which have had a profound impact on the shape of the prescription drug industry in Canada. First, in 1969 the federal government amended the Patent Act to allow compulsory licenses to import the active ingredients in pharmaceutical products. Second, in 1971 it established the Drug Quality Assurance Programme (QUAD).

The effect of the first of these initiatives was most dramatic. In the years prior to 1969, when compulsory licenses to manufacture drug products were the main mechanism to control abuse of patent protection for prescription drugs, only 22 such licenses were granted; in the period from 1970 to 1978, 216 licenses were granted to import or to import and manufacture drug entities. The net result of this activity has been the growth of a generic manufacturing sector in Canada which offers competitive copies of many drug products. It is not surprising that such a drastic change in the industry has caused, and continues to cause, substantial debate.

This debate over the effects of Section 41(4) is now the subject of a federal Commission of Inquiry which is due to report its findings on December 31, 1984. Because compulsory licensing to import is the backbone for product substitution, and because product substitution is encouraged to a greater or lesser degree by most provincial governments as a means of controlling the retail cost of prescription drugs, the recommendations of the Eastman Commission could, particularly in the long-term, change the

face of public policy beyond recognition. Regardless of the nature of the Eastman Commission's recommendations, public concern over the retail price of prescription drugs will remain; if the result of the recommendations is to increase market exclusivity or patent protection for the multinational patent-holding firms, provincial governments will be forced to devise new ways to control this area of health care costs. In short, compulsory licensing to import has created a policy umbrella under which the provincial programmes can flourish--the removal of that umbrella will have as profound an effect on the retail pharmaceutical market as did its introduction. To spell out more specific implications would be well beyond this Commission's mandate; suffice it to say that the resolution of this issue will have a significant impact on all sectors of the retail prescription market.

The second federal initiative which had an important influence on the retail prescription market was in the area of providing information to health care professionals about the drug products available to them. The Drug Quality Assurance Programme (QUAD), established in 1971, published four issues of QUAD REVIEW between 1972 and 1975--the REVIEW contained information on drug quality, prices, clinical tests, and manufacturing standards. In a market characterised by the fragmentation of the purchasing decision, with doctors choosing the product, pharmacists delivering it, private and public third-parties paying, and consumers receiving the product, the intent of the QUAD REVIEW was laudable in that it acknowledged the importance of better 'consumer' information on the general comparability of products.

More importantly, the QUAD programme laid the groundwork for the provincial drug quality and assurance programmes--these in turn became the basis, generally speaking, for provincial product substitution measures designed to control prescription costs (25).

These two federal actions, therefore, provided the participants in the Canadian drug delivery system with, first, competition at the manufacturers' level, and, second, with information on the price and quality of available drug products. At the same time, provincial governments were introducing prescription drug reimbursement programmes (or, in the case of at least two provinces, altering existing programmes). The shape of these programmes differ, either incrementally or substantially, from province to province--it seems clear, however, that all have essentially the same goal of relieving some or all citizens of the financial burden of prescription drugs. Further, it is also clear that all drug reimbursement programmes have benefited from lower costs brought about by compulsory licenses to import, although the extent of the benefit achieved has depended in part on the particular structure of each provincial programme(25). Finally, many of the provinces have taken over and expanded for their own jurisdictions the work of the QUAD programme and publish provincial formularies which serve several purposes by including some or all of the following information--a list of reimbursable benefits, drug product reimbursement prices, information on interchangeability and exp'anatory and cautionary notes on certain drug therapies. The provincial programmes to control prescription drug costs were thus given not only a great impetus by the amendment to the Patent Act, but were also given some

leadership in the area of improving the information available to health care providers.

GOVERNMENT OF ONTARIO: LEGISLATION AND PROGRAMMES

The Ontario government also took its first steps in the areas of controlling prescription drug prices and drug reimbursement programmes during the 1970s. The three most important structural elements of the present system were introduced separately, and have been combined and/or amended over the years to adapt to changing conditions or to improve their effectiveness.

These elements are the PARCOST program introduced in 1970; the amendment to the Pharmacy Act in 1972 instituting permissive product substitution; and Ontario Drug Benefit in 1974. In these programmes and policies are embodied the general goals of providing reliable information on drug products to prescribers and pharmacists, the encouragement of the use of low-cost interchangeable drug products, and the reimbursement of presription drug costs for selected groups of Ontario citizens. In many respects, the task of this Commission is to discern those instances when these goals have been departed from, whether intentionally or not. It is, therefore, wise to understand the intent of these programmes and policies before moving on to examine their practical effects.

The PARCOST programme, introduced in 1970, has in its name its primary purpose--the provision to the public of "prescribed pharmaceutical products of quality at a reasonable cost".(53) The key to the programme is

information--through the PARCOST Comparative Drug Index, the Ontario Department of Health sought to inform Ontario prescribers and pharmacists of the availability of comparable drug products of quality and their relative prices. By doing so, the Department of Health hoped to encourage competition among comparable products by informing physicians, pharmacists, and hospitals of the choices available to them in prescribing and purchasing pharmaceutical products. As well, the Department of Health hoped to encourage efficient distribution and purchasing of drug products through the way in which product costs were listed in the Index--pharmacists were to use these costs as a guideline to the maximum they should pay when purchasing products listed in the Index. Further, the Index was intended to recognise manufacturers whose products met certain quality standards as determined by the Department of Health's Drug Quality and Therapeutics Committee. Finally, pharmacies which voluntarily participated in PARCOST were to use the prices listed in the Index as a guide for prescription pricing, and were to charge customers no more than the drug product cost listed and the PARCOST fee negotiated by the Department of Health and the Ontario Pharmacists' Association. Thus, overall, the PARCOST programme was designed as a voluntary effort to disseminate information to physicians, pharmacists, and hospitals on drug quality, price and comparability; to encourage pharmacists to purchase drug products efficiently; and to provide a pricing guide to help stabilise prescription prices.

The next major policy action taken by the Government of Ontario was to pass an amendment to the Pharmacy Act which allowed pharmacists to product

select when dispensing generically-written prescriptions and product substitute when dispensing open prescriptions, which set pricing rules for product selected and product substituted prescriptions, and which relieved prescribers and pharmacists of any civil liability for actions or proceedings which might arise from any injurious act caused by substituting or selecting drug products in accordance with Section 155. This legislation was intended to encourage the prescribing and dispensing of the lower-cost drug products brought on to the market by generic manufacturers following the amendment to the Patent Act; to ensure that the use of such products was to the economic benefit of consumers; and to protect physicians and pharmacists from liability as long as they prescribed and dispensed interchangeable products designated as such in the PARCOST Comparative Drug Index, and did so in accordance with Section 155.

Finally, in 1974, the Government of Ontario introduced Ontario Drug Benefit, a prescription insurance programme which now provides full coverage of the cost of prescriptions for Ontario citizens who are over 65 years of age, who receive Family Benefits, General Welfare, Vocational Rehabilitation, or who live in Homes for Special Care. The intent of Ontario Drug Benefit is quite simply to relieve these citizens of the burden of paying for their medications, whether prescription or over-the-counter drugs. The Drug Benefit Formulary, first published in 1974 and merged with the PARCOST C.D.I. in 1975, lists all drugs which are benefits under the programme and the reimbursement prices the Ministry of Health will pay to pharmacists for dispensing those products to eligible recipients.

An important element of both PARCOST and Ontario Drug Benefit is the dispensing fee negotiated for each programme by the Ministry of Health and the Ontario Pharmacists' Association. The two fees were quite distinct until 1979, although at various periods from 1975 on they were identical in amount [Appendix B]. Even now, when only one fee is negotiated, each fee has its own unique application. The PARCOST fee is the maximum fee which PARCOST participating pharmacies agree to charge for dispensing any prescription. As well, pharmacists who practise product selection or product substitution must, under Section 155 of the Health Disciplines Act, charge a dispensing fee no higher than the PARCOST fee. The Ontario Drug Benefit fee is simply the fee the Ministry of Health pays pharmacists for dispensing prescriptions to Ontario Drug Benefit recipients.

Certain components of PARCOST and Ontario Drug Benefit merit attention here in that they have an important effect on the operation of the retail prescription market in this province. These components are the market-place concept, the 34-day dispensing rule, and the Bailey method of listing prices for high volume drug products. Through these structures, the Ministry of Health has attempted to ensure that Ontario Drug Benefit operates fairly for both the payer, the Ministry of Health, and the pharmacists who provide services under the programme.

The market-place concept is used in several jurisdictions and was introduced in Ontario in 1976 as part of the Participation Agreement entered into between each pharmacy and the Ministry of Health in order for the pharmacy to be eligible for reimbursement for services provided to Ontario Drug Benefit beneficiaries. This concept states that the Ministry

of Health will reimburse the pharmacist the lesser of his/her "usual and customary price . . . charged the general public and the lowest price listed in the Index for the drug dispensed, together with the PARCOST fee". The intended result is to constrain pharmacists from charging the Ministry of Health more than a private customer, or conversely to ensure the Ministry of Health benefits from any lower costs enjoyed by private customers.

The 34-day dispensing rule is also included in the Participation Agreement. It allows pharmacists discretion in the quantity of drug product dispensed on a prescription if the quantity prescribed is for more than one month's treatment. The benefit of this rule is perceived to be both economic and therapeutic. The economic benefit accrues to the pharmacist in that more fees can be collected from one prescription than would be the case under a "dispense as written" rule. It can be argued that the benefit is not insignificant with respect to Ontario Drug Benefit prescriptions in that senior citizens tend to be heavier users of maintenance medications than other population groups; it is estimated by the Ministry of Health that approximately 70% of all Drug Benefit claims are for maintenance medications. The therapeutic benefit lies in greater frequency of contact between the consumer and the pharmacist, thereby allowing improved monitoring of drug reactions and reducing the possibility of non-compliance and wastage.

Finally, the Bailey method of price listing of certain drug products is that component which relates most directly to this Commission's Terms of Reference. Following the recommendation of the Bailey Committee made in

1978 regarding the method for listing the prices of high-volume drugs, the Index/Formulary prices of thirty-six drug products, the monthly usage of which in 1979 exceeded 450,000 units for each product, were listed for package sizes of 1000 instead of 100. The purpose of this change was to adjust the listed prices of these drugs to conform more closely to the purchasing practices of pharmacists. At the same time, the Ontario Drug Benefit fee was adjusted upward by 22 cents to compensate pharmacists for the reduction in their reimbursement for drug costs caused by the Bailey listings.

These, then, are the major policies and programmes undertaken by the Government of Ontario since the late 1960s. Taken together, they represent government action in the retail prescription market on three fronts--dissemination of information on the price, quality, interchangeability, and availability of drug products; encouragement of the use of low-cost generic drug products by prescribers and pharmacists; and prescription drug insurance for certain groups of Ontario citizens.

As a final step before proceeding to an analysis of the way in which these programmes operate, the characteristics of the market in which they operate must be considered. Through these characteristics, some appreciation can be gained of the magnitude of the impact of the provincial government programmes on the provision of pharmaceutical services throughout the province.

ONTARIO RETAIL PRESCRIPTION MARKET

With respect to market segments, the Ontario prescription market can be divided into two distinct parts--prescription services which are reimbursed under Ontario Drug Benefit, and those which are not [Appendix C]. This latter sub-market can itself be divided, though much less clearly, into those prescription services which are reimbursed by private third-party plans and those which are not.

The Drug Benefit market is the most well-documented of the three. Beginning with a beneficiary population of about 600,000 in 1974, Drug Benefit now provides 100% coverage for prescription costs to 1,300,000 eligible Ontario citizens. This growth in the beneficiary population is caused by the expansion of eligibility in the early years of the programme and by growth in the eligible population. Drug Benefit beneficiaries, therefore, represent approximately 14.6% of the provincial population; within the beneficiary group itself, 890,000 (68.5%) are over 65 years of age.

Although Drug Benefit beneficiaries represent only 14.6% of the provincial population, their prescription volume as a percentage of all Ontario prescriptions is disproportionately high at 45%, primarily because of the predominance of senior citizens in the Ontario Drug Benefit group and their extensive use of maintenance medication.

Reimbursement to pharmacies for services provided to these beneficiaries has of course grown over the years as well. The factors contributing to the steady increase in the reimbursement paid to pharmacies are several: first, as already mentioned, the eligible population has

increased in size; the number of claims paid has grown--partly through growth in the eligible population, but also, it would seem, at least partly through an increase in the average number of claims submitted on behalf of each recipient; third, the negotiated fee has increased from $2.05 in 1974 to its current $5.00 level; and finally, drug costs have risen--partly because of an expansion in the number of drug products included as benefits, and partly because of the steady upward trend of reimbursement prices as listed in the Formulary, and the trend toward an increasing number of single-source high-cost therapies.

The remainder of the market is not as well documented as the Drug Benefit segment. Available information indicates, however, that private drug reimbursement and insurance plans operate extensively in this part of the market--it is estimated, for example, that of the 7.6 million residents not eligible for Drug Benefit, only 1.3 million do not participate in some type of third-party reimbursement plan. Thus, approximately 6.4 million Ontario residents enjoy some form of coverage for prescription medications. A variety of firms offer such coverage--of the estimated 33 private third-party payers in Ontario, some are profit, some are non-profit, and the coverage they provide ranges from premium plans to "flow-through" plans to those with co-payment, co-insurance, or deductible features. Finally, there are also several federal and provincial government agencies which provide prescription coverage to employees or clients--Workman's Compensation Board, Department of Veterans' Affairs, Department of National Health and Welfare, the Canadian Forces, and the Royal Canadian Mounted Police.

The volume of business done in the Ontario retail prescription market is estimated to be approximately 55,000,000 prescriptions in 1983/84. Of these, the Ministry of Health estimates that 25,216,600 will be for Ontario Drug Benefit beneficiaries, and 30,000,000 for all other citizens. The average prescription price in the Ontario Drug Benefit market is $11.57 for a total annual dollar volume of $291,763,600. The private third-party and cash segments of the markets will, therefore, have a prescription volume of 29,783,400 in 1983-84. The average prescription price in these segments is somewhat higher at $12.24 than for Ontario Drug Benefit prescriptions for a total annual dollar volume of $364,548,820. Overall, the Ontario retail prescription market in 1983/84 has a dollar volume of $656,312,420.

As will be discussed later in this report, the Ministry of Health's programmes and policies are not, nor are they intended to be, restricted in their influence to the Ontario Drug Benefit segment of the market. Through PARCOST, through the Index/Formulary, through Section 155, and through the negotiated fee, the Ministry of Health plays a substantial role in shaping the non-Ontario Drug Benefit part of the market. Thus, the task before the Commission is, in its broadest sense, to look beyond Ontario Drug Benefit to the entire market, and to consider at all times the impact of public programmes not only on all parts of the market but also on all participants in the system.

B. Function of Main Structural Elements

The three main structural elements of Ontario's public programmes are the PARCOST C.D.I./Drug Benefit Formulary, and, in particular, the prices listed therein, the negotiated dispensing fee, and Section 155 of the Health Disciplines Act. The following description of the uses to which these elements are put, and the ways in which they affect the participants in the retail prescription market, is intended to provide an overview of the operation of this market as well as an appreciation of the interrelated functioning of these elements.

PARCOST C.D.I./DRUG BENEFIT FORMULARY

The PARCOST C.D.I./Drug Benefit Formulary is central to the provision of prescription services in Ontario. Although the Index and the Formulary are printed as one document, each serves different functions, some of which overlap. The Index is the list of drug products certified as interchangeable by the Ministry of Health and their relative prices. The Formulary is the list of benefits available free of charge to Ontario Drug Benefit beneficiaries and the reimbursement prices pharmacists are paid for dispensing such benefits. The two overlap in the listing of interchangeable products.

To have its drug product listed in the Index/Formulary, a drug manufacturer must, first of all, have received a Notice of Compliance from the Health Protection Branch of Health and Welfare Canada certifying that

the drug product has federal government approval to be marketed in Canada. This notice must be submitted to the Drug Quality and Therapeutics Committee of the Ministry of Health, along with additional documentation, the nature of which depends on whether the manufacturer is applying to have its product accepted as a new listing, or as an addition to an existing listing, that is, as an interchangeable product. Some of the information required for the two types of application is the same, such as marketing and distribution information. Application for listing an interchangeable product, however, must be accompanied by more extensive documentation of the chemical and clinical properties of the product.

The cost which is listed for each drug product is intended to be the price which an average community pharmacy would pay to purchase one package of the most economical, efficient package size for that pharmacy. At the Ministry of Health's request, manufacturers provide a price for listing in the Index/Formulary for each of their products. The Ministry verifies these prices by checking them against price information from a variety of other sources, and discusses them with the manufacturers before finally accepting them for listing. These prices serve purposes related to both the Index and the Formulary. For the Index, that is, for the list of interchangeable products, the prices show the cost of purchasing one product relative to the cost of purchasing a product with which it is interchangeable. As well, for PARCOST participating pharmacies, these prices represent the maximum cost the pharmacy will charge the non-Drug Benefit customer for that drug product. For the Formulary, the prices listed for single-source and non-interchangeable products, and the lowest

price in each group of interchangeable products is the Maximum Allowable Cost, the amount which the Ministry of Health will reimburse pharmacists for dispensing those products to Drug Benefit recipients.

With respect to reimbursement, the intention of defining the reimbursement price as the price an average community pharmacy would pay for one package of the most efficient and economical package size for that pharmacy is twofold: first, to ensure that community pharmacies do not have to pay more for drug products than they will be reimbursed for them; and, second, to encourage efficient purchasing by allowing pharmacies to increase their revenue through purchasing advantage--the less a pharmacy pays to purchase a drug product, the more its reimbursement for that product represents additional revenue, which the pharmacist may choose to forego by only charging the customer the acquisition cost of the drug product. Thus, the reimbursement prices are designed to ensure a strong retail distribution system by supporting community pharmacies, and to encourage efficient buying through the financial bonus of purchasing advantage.

In addition to these official purposes, the prices listed in the Index/Formulary serve some unofficial purposes. The first, and most important, of these is their use by pharmacies as a pricing guide for non-Drug Benefit prescriptions, regardless of whether the pharmacy participates in PARCOST or not. Although the exact extent of this practice is unknown, the Commission believes, given the information provided by various pharmacy associations in Ontario, that it is widespread. The second unofficial purpose for which the prices are used is as a

reimbursement guideline for private third-party payers. Depending on the type of reimbursement plans, third-party payers, at the very least, compare prescription claims to Index/Formulary prices; in some cases, reimbursement for drug costs is capped at Index/Formulary prices.

The third and final purpose to which the prices are put is as a part of the manufacturers' marketing strategies. While the listed prices for interchangeable products were intended to provide a basis for comparing products, some manufacturers have extended this purpose by submitting prices for listing which exceed the price for one package of the defined size. By doing so, a manufacturer can increase the reimbursement paid to pharmacies for dispensing its product, thereby increasing the cost/price differential revenue available to pharmacies. In the end, manufacturers who inflate their Index/Formulary prices are choosing to compete, at least in part, on the payment pharmacies will receive for dispensing their products, rather than on their selling prices to pharmacies. In short, these manufacturers are using public funds in the form of cost/price differential to sell their products. Although the exact extent of this practice of spread-pricing is not known, and probably cannot be known given the fluidity of manufacturers' prices for prescription drugs, estimates from the Ministry of Health of the amount of public funds paid out in drug cost reimbursement based on inflated prices in 1983 range from $14,500,000 to $23,000,000.

Of all the unofficial purposes to which the listed prices are put, this latter has caused the most controversy. It has been addressed in two previous reports--the Report of the Review Committee on Prescription

Product Substitution (the Porter Report) in 1971, and the Report of the Ontario Drug Benefit Formulary Pricing Committee (the Bailey Report) in 1978. Both reports deplored this practice as a distortion of the reimbursement system. That the problem continues to exist, and that most of the parties involved in the Ontario prescription market do not support this practice, speaks to the need for this Commission, and to the willingness of the interested parties to restore the provincial government's drug reimbursement programme to its original principles.

In order to assess the impact of spread-pricing on pharmacy revenue, the Ontario Pharmacists' Association commissioned Woods Gordon to perform a study on pharmacy financial performance. The study formed part of the O.P.A.'s submission to this Commission. Although Woods Gordon indicated to the Commission that their study would provide more information on dispensary costs and their behaviour, the study's main focus was on trends in gross margins and net profits since 1979 with the intent of determining whether pharmacies had received undue profits during the period when it is alleged that the practice of spread-pricing was increasing. The study does provide some useful information about pharmacy operations. However, as Woods Gordon acknowledges in its report, its findings are not conclusive primarily because of problems with the representativeness of the sample, and with the model used. In the end, the Commission believes it is more important for all parties to prevent the recurrence of spread-pricing than to expend resources trying to determine the exact extent of its impact.

PARCOST AND DRUG BENEFIT DISPENSING FEES

The second structural element which is fundamental to the retail prescription market in Ontario is the dispensing fee, the other half of the pharmacy reimbursement concept of 'drug cost plus fee'. Ontario pharmacists receive a different amount of fee depending on which market they serve in dispensing a particular prescription, and depending on whether or not they product select or substitute on a particular prescription. In the non-Drug Benefit market, with the exception of product selected or substituted prescriptions, and with the exception of all prescriptions dispensed by PARCOST participating pharmacies, the dispensing fee is not regulated, and is now usually between $5.00 and $5.60 per prescription. Although the application of the fee is not uniform, being replaced or supplemented by a mark-up on drug cost in some instances, it applies generally to the bulk of the non-Drug Benefit prescriptions dispensed. PARCOST participating pharmacies agree to charge a fee no higher than the negotiated fee, currently $5.00, and all pharmacies are restricted by Section 155 of the Health Disciplines Act to the negotiated fee when dispensing product selected and substituted prescriptions.

The dispensing fee, whether negotiated or not, is thus intended to provide adequate remuneration to pharmacies for their professional services and for their costs of providing those services. This remuneration with respect to the Drug Benefit programme is augmented by purchasing advantage and by the 34-day supply rule. In practice, just as the listed prices serve purposes beyond those intended, the dispensing fee is not always

interpreted or used as it should be according to the cost plus fee concept.

The first departure from this concept arises from the mechanism of purchasing advantage--by allowing and encouraging pharmacies to generate revenue through drug cost reimbursement, the distinction between drug cost and dispensing fee has become blurred. As a result, pharmacies have, in a sense, come to look at their reimbursement as no longer having two parts but rather as comprising a total revenue package, and to seek to compensate for deficiencies in one component by increasing the amount of the other. That this is the case is borne out by a variety of arguments advanced to the Commission about pharmacy revenue. It has been argued, for example, that the negotiated fee has been kept at a less than adequate level because of the revenue pharmacies receive from puchasing advantage. More to the point, on two occasions when listed prices have been adjusted downward, the negotiated fee has been adjusted upward.

The second unintended purpose to which the negotiated fee is put is as a bargaining tool by the Ontario Pharmacists' Association. Again, the situation is one of a blurred distinction, this time between the Drug Benefit and the non-Drug Benefit markets. It is apparent that when the Ministry of Health and the Ontario Pharmacists' Association negotiate the Drug Benefit dispensing fee, the discussion is not confined (nor, possibly, can it be confined) to the fee paid to pharmacists for providing services to Drug Benefit recipients. Rather, pharmacists consider their total dispensary revenue (Drug Benefit and non-Drug Benefit alike) and make it clear that they will adjust the dispensing fee they charge in the non-Drug Benefit market if the negotiated fee is unsatisfactory.

Thus, it is clear that a cross-subsidy takes place; what is unclear is the net direction of the subsidy.

Finally, the negotiated fee is used by private third-party payers in much the same way as the listed prices. At the very least, claims for reimbursement are compared to the negotiated fee; in some instances, claims are capped at the negotiated fee.

Overall, therefore, the negotiated fee is tied, in practice, to the level of drug cost reimbursement, and is tied to the non-Drug Benefit market not only through legislation but also through the bargaining precedents established over the past decade. As with the listed drug prices, this element of the Drug Benefit programme is not independent of the non-Drug Benefit marketplace. Intertwined with the listed drug prices, and influencing and being influenced by the non-Drug Benefit market, the negotiated fee has a considerable impact on the entire retail prescription market.

SECTION 155, HEALTH DISCIPLINES ACT

The third structural element of Ontario's public programmes which it is important to consider is Section 155 of the Health Disciplines Act. This section of the legislation governs the practice of product selection and product substitution by pharmacists. The two primary aspects addressed are, first, the products eligible for being selected or substituted in both markets, and, second, the pricing rules for product selected or substituted prescriptions in the non-Drug Benefit market.

The intent of this legislation is threefold: to permit physicians and pharmacists to prescribe and dispense certified interchangeable products; to ensure that the prescribing and dispensing of such products is to the economic advantage of the consumer; and to protect physicians and pharmacists from any actions or proceedings which may arise from injurious acts caused by the prescribing or dispensing of interchangeable drug products. Section 155, therefore, is designed to be complementary to the objectives of the PARCOST Index--publishing a list of interchangeable drug products without having legislation allowing selection and substitution and protection from liability would considerably weaken the programme.

The impact Section 155 has on the Drug Benefit part of the market is quite different from the impact it has on the non-Drug Benefit part of market. For Drug Benefit prescriptions, pharmacy reimbursement is restricted to the lowest listed price in an interchangeable category, a practice which is commonly known as mandatory price substitution. Thus, regardless of whether substitution takes place or not, the pharmacy is reimbursed as if the lowest cost product had been dispensed. Although the extent of actual product substitution is unclear, the financial benefit of mandatory price substitution is unequivocal--the Ministry of Health estimates that it realises annual savings of $23,000,000 from price substitution.

In the non-Drug Benefit market, however, mandatory price substitution does not apply, nor, for that matter, does product substitution take place to any great extent. According to estimates given the Commission, of all prescriptions written about 20% are written generically and must be product

selected, and another 40% are written for brand-specific multiple-source products, and are, therefore, eligible for product substitution. Substitution, however, takes place on only about 6% of all prescriptions, or 15% of those prescriptions eligible for substitution. The savings being lost to the consumer by this low level of substitution are considerable. Using mandatory price substitution as a guide, about $2.15 could be saved on the 12,000,000 eligible prescriptions in the non-Drug Benefit market for a total annual saving of $25,800,000. Since product substitution is practised on only about 15% of these, or 1,800,000 prescriptions, and since mandatory price substitution is not the rule on these prescriptions, the actual savings are certainly no more than $4,000,000 and likely much less.

The primary unintended effect of Section 155, therefore, is that it does not fulfill its purpose in any meaningful way except when supported by mandatory price substitution in the Drug Benefit market. That this is the case seems clear; why it is so is a different matter. The Ontario Pharmacists' Association argues that the only substantial barrier to product substitution is the restriction on the dispensing fee. It may also be that spread-pricing, which occurs primarily on interchangeable products, has distorted the listed prices sufficiently to make product substitution disadvantageous either to the pharmacist in that s/he may suffer spread revenue loss by substituting, or to the consumer in that s/he may not receive the full economic benefit of substitution through having to pay an inflated price.

The purpose of this third structural element, therefore, seems to have been overwhelmed by the influence of the first two structural elements--the

Index/Formulary and the fee. Rather than acting in concert with these elements in the non-Drug Benefit market, it is defeated by them. It is only in the Drug Benefit market, and through the vehicle of mandatory price substitution, that Section 155 fulfills its purpose.

C. Analysis of Current System

From the foregoing, it can be concluded that Ontario's prescription drug programmes do meet, in most instances, their stated objectives. It is, as has been stated before, their unintended effects and their failure to meet certain objectives which is the concern of this Commission. By considering each programme with respect to its objectives, and with respect to the Terms of Reference, we can see that the issues identified by the Terms of Reference--listed prices, dispensing fee, and product selection/substitution--have a very direct bearing on the relative success of PARCOST, Ontario Drug Benefit and Section 155.

PARCOST

PARCOST, for example, was described in several submissions received by the Commission as an unpopular programme, or at least a programme whose day has passed. The fact that only 15% of Ontario's approximately 1,900 pharmacies are PARCOST pharmacies seems to bear out this description. However, upon closer examination, it seems evident that, by convention at least, PARCOST is still a significant force in the Ontario prescription market. The PARCOST Comparative Drug Index still provides information about interchangeable products, still promotes competition among drug companies, still identifies manufacturers whose products meet provincial standards of quality, and still provides a pricing guide for pharmacists.

The two main ways in which PARCOST principles have fallen by the

wayside are, first, through the inflated prices listed in the Index for some interchangeable products, and, second, through the abandonment of voluntary participation in PARCOST, and, therefore, the practice of charging the PARCOST fee. With respect to inflated prices, this represents a very serious distortion of PARCOST objectives. With the use of such inflated prices, pharmacy purchasing decisions may no longer be based primarily on anticipated demand, acquisition cost, and quality, but may, rather, be heavily influenced by the spread available on any particular manufacturer's product. The most serious consequence of this is that the consumer, whether individual or institutional, pays the inflated price for the drug product insofar as the pharmacy uses the Index/Formulary as a pricing guide. The precise extent and magnitude of the practice of inflated pricing is unknown; however, if the Ministry of Health, protected as it is by Maximum Allowable Cost, estimates that it paid out at least $14,500,000 in 1983 because of spread-pricing, it can be reasonably estimated that non-Drug Benefit consumers paid out considerably more than that in the same year.

Compared to this, the abandonment of the PARCOST dispensing fee becomes relatively less significant in monetary terms. The difference between the PARCOST fee and the marketplace fee is now about $0.35--on 30,000,000 prescriptions, this represents $10,500,000. The equally serious aspect of this use of the marketplace fee is the remarkable lack of competition among pharmacies. With only negligible consumer awareness that part of the price paid for prescriptions is a dispensing fee, and with strong reluctance on the part of pharmacists to provide such information, it is

difficult to see how the marketplace fee represents anything other than a pharmacy's view of the fee it should receive, rather than a fee acceptable to both the providers and receivers of pharmacy professional services. The marketplace fee in no way reflects any of the competitive behaviour which is normally associated with the market mechanism.

When spread-pricing and a non-competitive fee are combined, therefore, PARCOST becomes a programme whose primary goal—prescriptions at reasonable cost—has been subverted. This is not to say that PARCOST's other objectives, met as they are by convention rather than agreement, are unimportant, nor that the primary goal should be abandoned. And, indeed, the fact that nearly every group with whom the Commission met deplored the practice of spread-pricing indicates a willingness to work toward a system which embodies and enforces more realistic drug prices for all consumers.

ONTARIO DRUG BENEFIT

The Drug Benefit programme, like PARCOST, meets most of its original objectives. The programme provides 100% prescription coverage to certain groups of Ontario citizens; ensures, through the work of the Drug Quality and Therapeutics Committee, that the drug products provided as benefits are of high quality and therapeutic effectiveness; informs prescribers and pharmacists of available benefits and their reimbursement prices through the Formulary; reimburses pharmacies through the negotiated fee, the thirty-four day supply rule, and purchasing advantage; and attempts to control total programme costs through mandatory price substitution and the

marketplace concept. One important indication of the acceptance of this programme is the fact that virtually all pharmacies in Ontario have signed Participation Agreements with the Ministry of Health to provide services under Ontario Drug Benefit.

It is in the area of controlling costs that Drug Benefit is weakest and, again, spread-pricing is at the root of the problem. As has been mentioned earlier, the Ministry of Health estimates that drug reimbursement payments were inflated by at least $14,500,000 in 1983. Viewed solely in monetary terms, this problem is serious enough. Viewed in terms of the overall programme, the implications of this problem are much more disturbing. First, the very persistence of the problem, identified as early as 1971 in the Porter Report, calls into question the adequacy of the Ministry of Health's control over the prices that are listed in the Index/Formulary. Second, the programme as it now exists is put in jeopardy as long as this problem persists. This jeopardy arises in two ways. First, unjustified cost escalations bring with them the potential for budget restraint which could cause a drastic reshaping of the programme, whether through reduction of benefits or beneficiaries, the introduction of user fees, or by some other means. Second, unless the Ministry of Health can ensure that the programme is not being abused, and that the public funds spent on it are being spent responsibly, the Ministry may need to change its relationship with those who deliver dispensing services and practise a much greater degree of direct intervention. In the short term, therefore, the problem of inflated prices is a monetary problem and centres on the use of the system to the benefit of all except the consumer and the

taxpayer. In the long term, the problem is one which, if left unsolved, may have far-reaching consequences both for those who use, and those who deliver, prescription services in Ontario.

SECTION 155, HEALTH DISCIPLINES ACT

Finally, when we consider Section 155, we find that its performance in meeting objectives is, first of all, unequal between the two parts of the market, and, second, hampered by inflated prices. The effect of spread-pricing on inventory decisions exists primarily, if not exclusively, on the interchangeable products through whose existence consumers are supposed to benefit. And spread-pricing is in no way beneficial to consumers--pharmacies are encouraged to purchase products not on the basis of the attractiveness of the acquisition cost but on the attractiveness of the spread revenue available; even when product substitution takes place, therefore, the consumer is paying the lower of two or more inflated prices, not the lower of two or more realistic prices. The expressed reluctance of pharmacies to be restricted to the PARCOST fee when product substituting or selecting is the least serious of the problems in this area--even if the restriction on the fee were lifted, the fundamental purpose of providing an economic benefit through interchangeable products would still have to be salvaged through action on spread-pricing. Further, it should be noted that many pharmacies already charge their usual and customary fee when product selecting or substituting. It is possible that amending the legislation will only make this practice

legal, rather than provide an incentive for product substitution.

ISSUES

When we turn, then, to the Terms of Reference, we see that the pricing of multiple-source products is and must be the core of the Commission's concern. The issues that are raised by the pricing of multiple-source products range from the specific to the general. The specific issues are, first, if some form of drug product price list is to be published, should that list still attempt to perform all the functions it now does and how can prices be determined for listing so those functions are carried out properly? Second, if continuing to publish a list is advisable, although it always carries with it the risk of the problem of spread-pricing recurring, how can this recurrence be prevented? Third, has the revenue received by pharmacists from spread-pricing, although unintended, been necessary to bring pharmacy reimbursement to an adequate level? This leads to the fourth issue, that spelled out in the second Term of Reference--if the basis for listing prices is changed, should the implementation of that change be accompanied by an upward adjustment of the negotiated dispensing fee?

The more general issues that form the background to these specific issues are, first, how can the Ministry of Health best perform its several roles of regulator, payer, and trustee of public funds? Second, how can the Ministry's policies and programmes best be structured to ensure the efficient and effective operation of the retail prescription market in

Ontario? And, finally, how can better relations among government, pharmacists, and manufacturers be established?

Before attempting to address these issues through recommendations, the Commission considered carefully the relationship of each group of participants in the prescription market to the structural elements of the present policies and programmes, and its view of the current problems. A brief review of this process can assist in bringing into focus the varying objectives being pursued throughout the system, and the interdependence of all participants in the market.

MINISTRY OF HEALTH

The Ministry of Health, of course, holds a position of considerable importance as represented by its three roles. It regulates prescription prices in the non-Drug Benefit market through PARCOST, through the publication of the Index/Formulary, and through Section 155. It purchases 45% of the dollar value of all drug products and prescription services provided in Ontario. And, finally, it is held accountable for the responsible and appropriate use of public funds.

The Ministry's objectives, therefore, are simple enough. It aims to ensure that prescription prices in Ontario are fair to both the buyers and sellers of those services by setting appropriate market rules and procedures in place. It aims to ensure, therefore, that neither it nor any other purchaser of prescription services pays more than necessary, and that service providers in turn are adequately paid. It aims, as well, to

operate its programmes and policies as they are intended to operate and in such a way as to stand up under public scrutiny.

From the foregoing, it is no surprise that spread-pricing is the Ministry's primary concern, since this practice undermines all the Ministry's objectives. The Ministry's position on this matter is quite clear--if realistic prices can be re-introduced into the present system and maintained, the Ministry is satisfied that the system will work as it should.

ONTARIO PHARMACY

Ontario pharmacists also hold an important position in the market since, without their co-operation, the Ministry's programmes would not have been as successful as they are. The objectives of Ontario pharmacists, as represented by O.P.A., are twofold: to provide professional health care services of high quality to the people of Ontario, and to be paid appropriately for those services. That they meet the former objective consistently is abundantly clear. The latter objective, however, is a matter for conflict between the O.P.A. and the Ministry, with the focus of the disagreement being spread-pricing. The O.P.A. maintains that, although pharmacists do not endorse the practice of spread-pricing, the revenue they receive from it has been necessary to offset, first, the lack of any purchasing advantage on some drug products, particularly single-source products, and, second, a negotiated fee which is less than adequate. The Ministry, on the other hand, argues that the negotiated fee is adequate, and that the combination of purchasing advantage, a fee that

has risen with the CPI, and the thirty-four day supply rule provide a fair return for pharmacy. Thus, with regard to the second Term of Reference, O.P.A. argues for an adjustment to the dispensing fee whenever the basis of listing prices is changed, and the Ministry argues against it. The two parties, therefore, find common ground in their desire for listed prices to be more realistic; they part company after that on the extent to which drug cost reimbursement and negotiated fee should be separate.

To an even greater degree than the Ministry of Health, the O.P.A. supports the current provincial programmes. Whereas the Ministry of Health appears prepared to consider dramatic changes if required, the O.P.A. asserts that only incremental, minor changes are required. They suggest, for example, that the basis for determining whether wholesale or direct prices are listed should be changed, that the marketplace fee should be allowed on product selected and substituted prescriptions, that the costs of dispensing expensive drug products and over-the-counter products should be recognised, and that the Ministry's payment cycle should be improved. It is interesting to note that of all parties presenting proposals to the Commission, the groups representing pharmacists--the O.P.A., the Metropolitan Toronto Pharmacists' Association, and the Society for Independent Community Pharmacists of Ontario--were the least willing to entertain suggestions of significant structural change.

CANADIAN DRUG MANUFACTURERS ASSOCIATION

The organisations representing manufacturers, on the other hand, were markedly more willing to consider and propose significant changes. The

Canadian Drug Manufacturers Association, which represents manufacturers of generic drug products, recommended, for example, that the Ministry of Health play a much stronger regulatory role in the non-Drug Benefit marketplace by simply restricting all pharmacies to charging the Maximum Allowable Cost for prescription drug products. Admitting that spread-pricing was certainly used by some manufacturers as a competitive tool, the C.D.M.A. suggested that, while its members would be unwilling to see the Index of interchangeable products abandoned, they would like to see only one price, not necessarily the lowest and not manufacturer-specific, listed against any one group of interchangeable products. By only listing the Maximum Allowable Cost, the Ministry of Health could, according to C.D.M.A., essentially eliminate the vehicle used for spread-pricing, and by doing so, encourage manufacturers to be more competitive in establishing selling prices below the Maximum Allowable Cost.

Just as Ontario pharmacists are essential to the provision of prescription services, the members of C.D.M.A., producing as they do lower-cost generic drug products, are essential to any public policy aimed at keeping prescription costs within reason through either product or price substitution. And, in turn, it is not surprising that C.D.M.A. supports those aspects of Ontario's programmes which promote its members' products--in particular, the Index and Section 155. By suggesting that the Ministry of Health strengthen these programmes by implementing mandatory price substitution throughout the market, C.D.M.A. is proposing a course of action which it believes to be of mutual benefit to its members and to all payers for prescription drug products, whether institutional or

individual.

Again, it is important to note that C.D.M.A. argues against the practice of spread-pricing. Since generic manufacturers may be assumed to be one of the groups which benefits from the additional sales generated by this practice, their willingness to see it eliminated extends yet further the common agreement that some means of establishing reasonable, realistic prices must be devised and implemented.

PHARMACEUTICAL MANUFACTURERS ASSOCIATION OF CANADA

The Pharmaceutical Manufacturers Association of Canada, the group representing the patent-holding manufacturers, argues as well against the present system of listing prices in that it invites spread-pricing. This group, however, proposes that the Ministry of Health adopt a less regulatory position in the market by publishing no more than a list of interchangeable products, by allowing all drug products approved by Health Protection Branch, Health and Welfare Canada to be benefits under the provincial reimbursement programme, and by reimbursing pharmacists using an actual acquisition cost system.

Focusing on the importance of having the widest possible range of products available for therapy, and asserting that the Special Authorization mechanism for including products not listed as benefits is ineffective, P.M.A.C. maintains that the Formulary is restricting drug therapy and thereby increasing the overall cost of health care. Again, this argument is consistent with the interests of the members of P.M.A.C. in being

able to market all their products without having to pass the provincial quality assurance programme as well as the federal. Whether this is a proposal that would work to the benefit of the general public is a matter for considerable debate given the current state of physician awareness of drug products and the equally strong assertions by some parties that the number of drug products available is not an equivalent measure of the effective therapy available.

The two most pertinent aspects, therefore, of the P.M.A.C. proposal are, first, that it recognises the legitimacy of interchangeable products, and second, that it includes a return to more realistic prices. Although P.M.A.C.'s proposal with respect to interchangeable products would certainly slow down the introduction of interchangeable products, and its own members' actions in creating a proliferation of single-source products are certainly an effective way of protecting themselves from generic competition, P.M.A.C.'s actual acquisition cost proposal does indicate a concern about prescription prices in Ontario.

The other groups from which the Commission received submissions ranged from a manufacturer not represented by C.D.M.A. and P.M.A.C., third party payers, and consumer groups to the Ontario Medical Association, the Ontario College of Pharmacists, and the major pharmaceutical wholesaler in Ontario, Drug Trading Company Limited. In one way or another, their views are represented by the proposals outlined above. The common themes of a return to realistic prices, the importance of interchangeable products, and general support for the objectives of the current programmes run throughout the submissions from these groups. Departures from this consensus emerge

only when solutions to the current problems are broached--some prefer more regulation on the part of the Ministry, some prefer less; many advocate more consumer education, some deny the benefits of this; and some see incremental changes to the current programme structure as sufficient, while others view the present structure as inherently faulty.

It is on the latter point that the submissions, in the Commission's opinion, can be most usefully grouped. While nearly all the organisations focused primarily on the problems caused by the current method of listing prices in the Index/Formulary, some organisations maintained that the problems could be solved within the present system; others argued that a different system altogether is needed. This disagreement, in the end, speaks to two overriding concerns: first, what are the true structural problems of Ontario's programmes as indicated by such symptoms as inflated prices and lack of product substitution; and, second, are these structural problems manageable or would a different type of programme offer the prospect, not necessarily of a perfect system, but of a system with fewer and less significant structural problems to be managed. Needless to say, both of these concerns, while focused on pricing, must also take into consideration other programme elements, such as the fee, as they influence and are influenced by the method of pricing drug products.

COMPETITIVE BEHAVIOUR IN ONTARIO'S PRESCRIPTION MARKET

In the Commission's view, and, we believe, in the view of at least some of the system participants, the fundamental structural problems of the

current programmes and policies are the singular lack of effective competition throughout the retail prescription market and, in those instances when some competition exists, the barriers preventing the benefits of such competition from being passed on to consumers. In short, while some elements of the present structure promote competition, other elements hinder it. The elements which hinder it are stronger than those which promote it--thus, the overriding objective of reasonable prices for prescription drug products and services is not achieved to an acceptable level.

Competition in this context does not necessarily mean complete absence of regulation. Rather, it means structures which encourage suppliers of services to provide those services at the lowest possible cost. Thus, for example, the reimbursement price ceiling imposed for Drug Benefit prescriptions through the use of Maximum Allowable Cost presumably encourages manufacturers to compete for sales to pharmacy by keeping their selling cost below the Maximum Allowable Cost. The question is whether these structures work as they should or whether they are less effective than intended because of the presence or absence of other structures.

Within Ontario's prescription market, competition can exist at a number of levels. Manufacturers can be competitive in their selling prices to pharmacies, wholesalers, and the Ministry of Health. Pharmacists can be competitive in their selling prices to individual consumers, and to private and public third-party payers. Consumers, both individual and institutional, can encourage competitive actions on the part of retail pharmacies by being knowledgeable about the products and services they are

purchasing and by using that knowledge to choose the pharmacy which offers them the most value for their money.

Given this brief identification of potential sources of competitive behaviour within the prescription market in Ontario, we can examine which structures can be used to encourage competitive behaviour, which are used to do so, and which structures discourage competitive behaviour. The structures which encourage competition include both those which are related to provincial policies and programmes, and those which are not. Those which are external to provincial action include such things as manufacturers' research and development and advertising activities, and compulsory licensing.

Those which are specific to Ontario, and merit the Commission's attention, are the PARCOST C.D.I., the Maximum Allowable Cost reimbursement price ceiling, Section 155, and Ontario Drug Benefit. Of these, only the reimbursement price ceiling is effective in any substantial way. The Index and Section 155, for example, attempt to encourage competition by providing information to prescribers and pharmacists on available lower-cost interchangable products and by permitting product substitution. This purpose is defeated in large measure in the non-Drug Benefit market by the current method of listing prices in the Index. Ontario Drug Benefit could also be used by the Ministry of Health to increase competitive behaviour on the part of both manufacturers and pharmacists. Through Drug Benefit, the Ministry of Health is an indirect volume buyer of pharmaceutical products, and could use its dominance in the marketplace in one of two ways. Within the present structure, the Ministry could conceivably take a stronger

position with respect to manufacturers in insisting that prices submitted for listing conform to the agreed upon definition. This would reinforce the effectiveness of the Maximum Allowable Cost price ceiling in the Drug Benefit market and would, more importantly, make price comparisons among interchangeable products more meaningful. As well, some price competition in the cash market would be encouraged as manufacturers would then attempt to increase the purchasing advantage available to pharmacies by lowering the acquisition cost. Or the present structure could be changed, and the Ministry could, on behalf of wholesalers and pharmacies, negotiate with manufacturers to establish guaranteed acquisition costs.

By not exercising its strength in the marketplace, the Ministry not only foregoes an important opportunity to control the costs of prescription drug products, it also restricts effective competition by accepting and publishing inflated prices. For their part, manufacturers take advantage of this chance to compete on the basis of spread rather than selling price, and pharmacies, by using the listed prices for non-Drug Benefit prescriptions and taking advantage of this unintended revenue opportunity, encourage manufacturers to continue to inflate listed prices.

The current method of listing prices is, therefore, one of the principal barriers to competition in the Ontario prescription market. As with structures encouraging competition, some of those which hinder competition exist outside the sphere of provincial action, such as patents, and the "first mover" advantage gained by patent-holding manufacturers. Those which are related to Ontario's public policies and programmes include, as described above, the present method of listing prices and the Ministry's

failure to use its strength in the marketplace, as well as the unequal distribution of information throughout the system, and the inability or unwillingness of those parties with information to use it or share it.

With respect to information, there are essentially five institutions or groups which could influence the operation of the Ontario prescription market if they used or could use the information they have, or if they had any information at all—these are physicians, pharmacists, the Ministry of Health, the private third-party payers, and consumers. Of these five, the latter has no access to the type of information required to have an impact on the market.

The information that physicians and pharmacists have that could act to lower prescription prices is the interchangeability information provided in the Index by the Ministry. Prescribers choose products on behalf of patients, and could use this information to specify the use of lower-cost products by writing either generic prescriptions or, when appropriate, prescriptions specifying a product supplied by a generic manufacturer. Choosing drug therapies rationally, and writing prescriptions generically are currently the most effective means prescribers have of assisting in controlling prescription costs.

Prescriptions which specify an interchangeable product by manufacturer but do not prohibit substitution are by far the majority of prescriptions written for interchangeable products. While it can be argued that such a prescription is a signal from prescriber to pharmacist to product substitute, in practice a more accurate interpretation is that the pharmacist still retains the discretion not to substitute a lower-cost

product. The fact that the estimated level of substitution on this type of prescription is considerably lower than possible indicates the present ineffectiveness of product substitution in the prescription market.

Turning to pharmacists, who decide which drug products to purchase and, in some cases, which to dispense, they too have the information on interchangeability provided by the Index; as well, they know the current market price of any drug product. Since product substitution does not take place to any appreciable degree, and since, as a general rule, non-Drug Benefit prescriptions are priced not according to acquisition cost but according to the listed prices, it can reasonably be asserted that pharmacists are not using their price and product information to ensure lower prescription prices for Ontario residents. With respect to drug prices, it is interesting to note that even though pharmacists are allowed to post drug prices, and even though they are allowed to advertise their provision of price information, almost without exception they do not do so. By not using the mechanisms available to provide price information (inflated or otherwise) to consumers, pharmacists are failing to share information which could increase competition. It has been asserted that price posting could lead to "shopping around" by consumers and a consequent erosion of pharmacy's ability to monitor drug usage. However, in the Commission's view, the factors which influence a consumer's choice of pharmacy are not known well enough to make this assertion; even if it is true, other mechanisms could be used to monitor drug usage.

Further, as noted earlier, the marketplace fee charged non-Drug Benefit customers by pharmacists is not the result of any competitive activity.

The present paucity of information relating to pharmacy operating costs prevents any accurate estimate of an appropriate fee; more important, however, in this context, is the fact that fee posting is not allowed in Ontario, and pharmacists have resisted previous suggestions that fee information would be useful to consumers. The arguments against fee posting focus on the belief that a pharmacy could attract customers by having a low fee while, at the same time, charging those customers the same total prescription price as a pharmacy with a higher fee by adjusting the retail cost of the drug product upward. This claim, if true, is disturbing in that it implies that pharmacists have not really accepted the drug cost plus fee concept, and will abandon it quite readily. In the end, however, the fact that pharmacists appear hesitant to find an effective way to share drug price and professional fee information with consumers indicates a certain unwillingness to take actions which could increase competitive behaviour in the market.

Some consumers, however, do have drug price and fee information--specifically third-party payers. The private third-party payers, whether profit or non-profit, do know the current fee levels, both negotiated and marketplace, and at least know the listed prices of drug products, if not in all cases the manufacturers' or wholesalers' selling prices. These institutional payers are hampered in using this information, however, in three ways: first, they are hard pressed to bargain lower reimbursement levels with pharmacies when the major institutional buyer in the market, the Ministry of Health, pays listed prices and the negotiated fee; second, they are subject to pressure from pharmacists to reimburse at least at Drug

Benefit levels or risk refusal by some pharmacies to fill prescriptions for their insured customers; and, finally, particularly for third-party payers offering reimbursement plans, the individual insured consumer is unable, without information, to act on behalf of the third-party payer in seeking out reasonable prescription prices. The long-range implication of the inability of third-party payers to act on the information they have is not good for either consumers or pharmacists--conceivably, as prescription prices rise, so will the cost of prescription insurance. Such insurance could well become, for example, much less attractive as an employee benefit and could, in some cases, be abandoned in favour of other benefits more amenable to cost control. As a result, consumers will be less protected from the cost of prescriptions than they are now, and pharmacists could be faced with a much larger cash paying population with the consequent problems of credit extensions, account collection, and bad debts.

Finally, the Ministry of Health has both the information required to influence the market and the ability to use that information. As has been discussed before, the Ministry does not use this ability as effectively as possible. Thus, overall, the information required to introduce some competitive behaviour into the retail prescription market is either not accessible to those who could use it, or unusable or unused by those who have it. The issue of consumer information is admittedly not an easy one--addressing the problems of what information should be available, and to whom it should be available is only the first step in attempting to encourage competitive behaviour through enhanced consumer education. For example, it may well be that drug price information is not appropriate or

useful to consumers in this context. However, the Commission believes that this is an area of concern which should be given careful consideration.

In considering the Terms of Reference, therefore, the Commission has found it useful to analyse the current structures according to whether they promote or hinder competitive behaviour in Ontario's prescription market, and whether the current regulations governing this market perform as intended or create conditions which undermine the objectives of PARCOST, Ontario Drug Benefit, and Section 155. The Commission wishes it to be understood that it does not blindly presuppose that in this market, the more competition the better. Rather, our approach has been to look for areas where some level of competitive behaviour would assist the functioning of public programmes and ensure the efficient and effective distribution of safe and therapeutically sound prescription drug products to the people of Ontario.

V. ALTERNATIVE APPROACHES

In addressing the issues raised by the Terms of Reference, the Commission has attempted to keep in mind the fundamental objectives of the provincial government's policies and programmes. These objectives include ensuring that the prescription drug products dispensed to Drug Benefit recipients are of high quality and therapeutic effectiveness, encouraging lower prescription prices by promoting the use of lower-cost interchangeable products, ensuring that pharmacies are adequately compensated for their services, and that all payers for prescriptions enjoy reasonable prices.

These objectives are not unique to the Ontario government--they are pursued, in one way or another, by all other provincial governments, and by the governments of many other countries. In the process of considering specific recommendations to resolve the problems being faced in Ontario now, the Commission investigated the programmes designed to meet these objectives in other jurisdictions.

Although there is considerable variety in the approaches used by other Canadian jurisdictions, one element is common to all systems--the use of the drug cost plus fee method of reimbursement. Beyond that, the programmes can best be classified in two ways--first, by the degree and rigour of market regulation practised by any particular government, and, second, whether the programme is universal or not. Our review, although cursory, revealed that no programme structure or policy approach is without problems, and that the effectiveness of any particular programme seems to

depend on both the consistency of its structure, and the level of co-operation and consultation exhibited by all participants.

BRITISH COLUMBIA PHARMACARE

Within Canada, the spectrum of programmes to reimburse the costs of prescription services ranges from the least regulated, most marketplace-oriented approach used by the British Columbia government to the much more highly regulated approach used by the Saskatchewan government. B.C.'s reimbursement programme, Pharmacare, provides 100% coverage to senior citizens (Plan A), residents of long-term care homes (Plan B), and people receiving Human Resources Medical Benefits (Plan C). These three Plans include about 492,000 people, or 18% of the provincial population. Approximately 5,800,000 prescriptions were reimbursed for this population in 1983 for a total payment to pharmacy of $82,912,000. As well, B.C. Pharmacare provides 80% coverage for prescription services for all other citizens (Plan E) after an annual deductible level of $175.00. In 1983, 114,889 claims were paid for this group with a total payment to pharmacy of $14,124,000. Overall, Pharmacare officials estimate that Pharmacare provides coverage for approximately 45% of all prescriptions dispensed in British Columbia.

Two points merit attention in any comparison of B.C. Pharmacare with Ontario Drug Benefit. First, as noted above, the effective coverage, with respect to percentage of population and percentage of prescriptions is essentially the same in B.C. as in Ontario. Second, although B.C.

Pharmacare is a universal program, the deductible applied to Plan E recipients is sufficiently high that many residents use private reimbursement plans to lower their threshold of financial responsibility--thus, the B.C. system, like that in Ontario, represents a mixture of private and public payers.

The structural elements of Pharmacare, however, are quite unlike those of Drug Benefit. Pharmacare benefits are not published in a formulary, but rather include all prescribed medications. Further, although substitution is permissive, the province does not certify interchangeability and does not protect physicians and pharmacists from civil litigation. Reimbursement to pharmacists is governed by the marketplace concept, and is composed of drug cost and fee, with drug cost being defined as actual acquisition cost and the fee as up to 15% over the previous month's provincial average depending on an individual pharmacy's declared level of third-party prescription business.

This flexible system of reimbursement is assisted by the practice among pharmacies of including both drug cost and fee information on prescription labels. Pharmacare staff monitor drug prices and fees throughout the province quite extensively, and have developed a strong and co-operative working relationship with B.C. pharmacies.

The main criticism levelled at Pharmacare from outside British Columbia is that drug cost reimbursement based on actual acquisition cost provides no incentive for pharmacies to purchase drug products in efficient quantities, and any savings from volume purchasing are lost to the consumer. This criticism is countered by the argument that a pharmacy's

need to keep enough inventory to provide good service is sufficient encouragement to purchase drug products efficiently. Overall, therefore, it appears that the Pharmacare system works well, and that any problems which do arise are assisted toward resolution by the ability of B.C. pharmacists and Pharmacare officials to work together well. For example, the provincial average dispensing fee recently showed increases beyond a level consistent with the provincial government's restraint programme. When notified of the provincial government's concern about this trend, the B.C. Pharmacists' Association agreed to an adjustment of the base fee upon which the provincial average is calculated, and offered to undertake a variety of other measures aimed at controlling Pharmacare costs, including increasing the practice of product substitution.

According to a senior official with Pharmacare, the programme is designed to be flexible enough to respond to new situations created by the dynamics of the marketplace. This flexibility is apparent in the innovative measures currently being introduced by Pharmacare to control the cost of prescription drugs and to advance the level of service being offered. Some of these include a trial capitation programme in Kelowna in which the participating pharmacies will receive a monthly per capita payment for each registered client and drug cost reimbursement for each prescription dispensed; the development of a software program for physician use in determining appropriate drug therapies; a trial prescription programme wherein customers receiving a new medication are given only ten days' supply in case of adverse reactions or other problems with compliance, and the pharmacist is paid drug cost and fee for the trial

quantity prescription, and drug cost alone if the rest of the quantity prescribed is dispensed; and, finally, a weighted average system for determining the Pharmacare dispensing fee by which a pharmacy's Pharmacare fee depends on its mix of publicly-funded and privately-funded dispensary business.

The operation of Pharmacare, therefore, exhibits an admirable facility to adapt to changing circumstances and to consider new approaches to cost control and service delivery. One measure of the success of these endeavours is the apparent health of independent pharmacies in the province; and, certainly, one structure which supports this success is the referendum mechanism used by B.C.Ph.A. to canvass its members' opinions on these innovations and to guide its dealings with Pharmacare.

SASKATCHEWAN PRESCRIPTION DRUG PLAN

At the other end of the spectrum in Canada is the Saskatchewan Prescription Drug Plan. Like Drug Benefit, SPDP publishes a Formulary of the drug products which are benefits under the Plan, and provides a method by which pharmacies may be reimbursed for drug products not listed in the Formulary. As well, the Drug Plan certifies the interchangeability of certain drug products, and backs this up with mandatory substitution legislation. One important difference between SPDP and Drug Benefit with respect to the products listed as benefits in the Formulary is that, in considering an application from a manufacturer to have its product listed, SPDP puts significantly more emphasis on comparing that drug with products

already listed on the basis of therapeutic effectiveness and cost. Thus, not only is drug quality and availability an important factor in accepting a drug product for listing, but also the product must have a demonstrated ability to make a contribution to effective therapy commensurate with its cost. In addition, products currently listed may be removed from the Formulary if new products are superior in their therapeutic and cost value. Thus, it would appear that SPDP uses its Formulary system as a means of controlling programme costs while providing a high quality range of products.

Another significant difference between SPDP and Drug Benefit is in the area of pharmacy reimbursement. Although, again, drug cost plus fee is the model used, SPDP reimbursement differs from Drug Benefit reimbursement in three significant ways. First, the pharmacy's dispensing fee, negotiated by the Saskatchewan Pharmacists' Association and SPDP, is paid jointly by SPDP and the consumer, with the exception of certain groups of special beneficiaries who are exempt from the co-payment. The maximum consumer copayment is currently $3.95, and may, at the discretion of the pharmacy, be lower. Second, the drug product prices listed in the Formulary are not intended to include purchasing advantage, but rather are meant to reflect the acquisition cost of the pharmacy and are based on current manufacturers' price lists. In addition, for high-volume products, SPDP awards a Standing Offer Contract (S.O.C.) to the supplier providing the lowest tender price. Through this mechanism, SPDP uses its influence in the marketplace to ensure the best possible prices are available to pharmacies and to the provincial government. Third, SPDP subsidises

smaller pharmacies through a two-tier fee system--a higher fee is paid on the first 20,000 prescriptions dispensed annually.

Other features of the Saskatchewan Prescription Drug Plan which are worthy of mention are the Joint Committee on Drug Utilization which studies utilisation patterns, recommends ways of dealing with any areas of concern, and provides information for the education of consumers and health care professionals; the Saskatchewan Formulary Bulletin which reviews current drug therapies and is published four times a year; the Dial Access programme which provides drug product information to health care professionals; the Roving Professorship programme which brings drug therapy information to pharmacies in smaller communities; and the Health Information Centre project which is jointly sponsored by the Saskatchewan Pharmacists' Association and SPDP to educate consumers on the use of prescription drugs and other health-related topics.

Thus, SPDP has two primary characteristics. First, through its fairly rigorous system of regulation, the Plan exercises control over costs by the S.O.C. method of establishing prices for high-volume drugs and by ensuring that those drug products which are benefits provide a significant therapeutic advantage at reasonable cost. Second, through the variety of education programmes offered, SPDP and the S.Ph.A. show a clear commitment and willingness to co-operate in the ongoing education of consumers and health care professionals about drug therapy.

Other provincial reimbursement plans fall between the two ends of the spectrum represented by British Columbia and Saskatchewan. Some are universal, such as Manitoba's, others are targeted for certain population

groups; some are administered by the provincial government, while others, such as Alberta's and Nova Scotia's plans, are administered by private insurance companies; some have formularies listing all benefits, while others list only multiple-source benefits; some reimburse pharmacies the provincial average selling price of the drug product, while others will reimburse up to a median ceiling price. While this variety of approaches makes inter-provincial comparison of costs difficult [Appendix D], the Commission believes current efforts to draw such comparisons are worthwhile and, if supported strongly, will be of benefit to all provinces as they attempt to provide their citizens with quality drugs at reasonable cost.

Beyond Canada, the policy approaches investigated vary even more dramatically. In France, for example, pharmacies are still reimbursed on a drug cost plus markup basis. Consumers pay pharmacies for prescription drugs, and then submit claims for reimbursement to the Caisse Nationale d'Assurance Maladie. Different percentage levels of reimbursement are applied to different groups of citizens and categories of drugs. Wholesalers' and pharmacists' margins are strictly regulated, as are manufacturers' initial selling prices and all annual price increases thereafter.

In the United Kingdom, prescription drug coverage is provided universally by the National Health Service; certain groups of citizens are responsible for a co-payment to the pharmacist on each prescription, while others are exempt from the co-payment. Manufacturers' selling prices are closely regulated, as are their advertising and promotion expenditures. Pharmacies are reimbursed by the National Health Service for drug cost and

fee, and the amount of drug cost reimbursement is adjusted downward the higher the monetary value of the drugs for which claims are submitted in a month, and adjusted upward the higher the number of prescriptions dispensed by the pharmacy in a month [Appendix E].

In the United States, on the other hand, a bewildering variety of reimbursement programmes and methods exists with federal and state governments and private plans all participating in the market. Some states have highly restrictive formularies which exclude, for example, high-volume drugs; others restrict coverage to two or three prescriptions a month for each recipient; and some operate drug utilisation review programmes to encourage rational prescribing. Reimbursement to pharmacies appears to be almost universally based on drug cost plus fee, with some private and public plans being quite innovative in their methods of fee determination. The State of Kansas, for example, tailors its fee to suit individual pharmacies based on voluntarily submitted tax return information. A private plan in New Jersey categorises participating pharmacies by the level of services offered, from basic dispensary service to 24-hour service with patient counselling and product substitution, and pays different fees to pharmacies in different categories.

Regardless of the variety of approaches used, it is clear that all prescription drug reimbursement plans are attempting to achieve the same goals--protection of some or all citizens from the costs of prescription medicine, provision of adequate and appropriate payment to service providers, ensuring the financial burden of these programmes is reasonable and controlled through a variety of measures such as product substitution,

contracted selling prices and incentives for efficient pharmacy purchasing, and, in some cases, ensuring that available drugs are of high quality. These are the goals of Ontario's Ministry of Health, and its means of achieving them and the problems it has encountered are not substantially different from the experience of other jurisdictions and private plans. As the Commission surveyed this variety of approaches, we realised that no system is free of fault, and that the strongest ally all participants can have in building a strong system is a spirit of co-operation and a willingness to work together toward solutions of mutual benefit. More practically, the Commission realised that, in resolving their current problems, the participants of the Ontario system have a wide range of options from which to choose, some of which are described in the foregoing review.

Essentially these choices involve the following decisions about the introduction of competitive behaviour into the retail prescription market. Should the Ministry of Health encourage more competitive behaviour on the part of manufacturers by calling for bids on the supply of high-volume drug products to Drug Benefit? Should more competitive behaviour be encouraged at the retail level, whether through consumer education, drug prices and fee posting, or a tiered fee based on services provided? Should the Ministry of Health move toward letting marketplace forces determine more directly their reimbursement to pharmacists, and, if so, what structures are required to do so? Or should the Ministry of Health move toward stronger regulation of the retail prescription market through extending some form of coverage to all citizens, and improving its monitoring of the

activities of manufacturers and pharmacists? And, finally, how can the main participants in the retail prescription market in Ontario become more proactive in their approach to problems as they arise, and more consultative and co-operative in their approach to problem-solving?

VI.A. PRIMARY RECOMMENDATIONS

The following recommendations address the specific issues identified in the Terms of Reference:

1. how should the prices listed in the PARCOST C.D.I/Drug Benefit Formulary for multiple-source products be determined?

2. should the negotiated dispensing fee be adjusted when the basis for drug cost reimbursement is changed?

3. should any changes be made to Section 155 of the Health Disciplines Act?

These recommendations are intended to provide a means by which the four principal parties can resolve the problems they now face, and a framework for ensuring these problems do not recur in a similar magnitude.

Some of these problems--spread-pricing in particular--have been evident over the course of many years, and have been addressed in the two major previous reports on Ontario's prescription drug policies and programmes. The recommendations put forward in these reports, most notably the Bailey Report, have not met with considerable success. Some have not been adopted; others have only been partially adopted; and still others have been adopted but have not been very effective. In the Commission's view, one of the most disturbing aspects of the issues it has been studying is that, for various reasons, those previous recommendations which have been sound and worthwhile have either been acted upon only partially or not at all.

Given this aspect of the history of Ontario's policies and programmes, the Commission gave serious consideration to whether or not major changes should be made to the present system. In the end, the Commission decided that its recommendations should introduce as little disruption into the

retail prescription market as possible. In short, it is the Commission's opinion that the current structures have no more inherent faults than any other structures which could be contemplated, and that the four principal parties would benefit most by recommendations which focus on strengthening this structure rather than abandoning it for another.

PRICING OF MULTIPLE-SOURCE DRUG PRODUCTS

The pricing of multiple-source drug products in the PARCOST C.D.I./ Drug Benefit Formulary touches every participant in Ontario's retail prescription market. As has been discussed earlier in this Report, the most serious abuse of the present pricing method is the practice of spread-pricing. All the principal parties deplore this practice, and seek a system which will ensure realistic prices. Such realistic prices should, in the Commission's view ensure, first, that no payer, whether private, public, individual or institutional, should pay inflated drug cost reimbursement to pharmacies; second, that pharmacies should be reimbursed at least to the level of the price at which they purchase drug products; and, third, that manufacturers receive a fair return and are encouraged to be price-competitive. The Commission recommends, therefore, that:

1. the Ministry of Health should continue to publish the PARCOST C.D.I./Drug Benefit Formulary in its present form, listing all drug products eligible for reimbursement under Drug Benefit and the Maximum Allowable Cost for each, and all drug products certified as interchangeable by the Drug Quality and Therapeutics Committee and their relative prices;

2. prices should continue to be listed for all drug products in an interchangeable group, and, for each manufacturer's product,

should be no more than 20% higher than the best volume price available from the manufacturer during the formulary period for the package size listed. This method of determining the price for listing could also be applied to single-source products. It is intended to maintain the concept of purchasing advantage with its consequent motivation for pharmacies to purchase efficiently and for manufacturers to price their products competitively. The exact percentage included in this definition (20%) is, of course, open to negotiation by the Ministry of Health and the Ontario Pharmacists' Association if they choose to change the amount of purchasing advantage available to pharmacies;

3. the Ministry of Health make it a condition of listing for any particular drug product that the manufacturer of that product sign an agreement with the Ministry of Health stating that the prices submitted are accurate and will be adhered to. The penalties which might be considered for any manufacturer not honouring such an agreement could range from ceasing reimbursement for that manufacturer's product to temporarily restricting reimbursement price increases for that manufacturer's product;

4. the Ministry of Health should continue to base the prices listed for high-volume drug products on package sizes of 1000. To improve the effectiveness of this policy, the Ministry should examine whether the definition of high-volume (450,000/month) needs to be revised, and should keep this group of high-volume drug products current by making additions and deletions regularly. As well, pharmacies and manufacturers should be given a reasonable amount of notice of changes in the drug products defined as high-volume;

5. the Ministry of Health should revise the prices listed in the Index/Formulary quarterly so that they reflect changing market conditions more quickly. The Index/Formulary should still be published twice yearly, and the Ministry should, therefore, investigate methods of distributing price information which guarantee both ease of revision and ease of use. One method which might be considered, for example, is the use of microfiches such as those employed by Drug Trading.

DISPENSING FEE

Although the negotiated dispensing fee is intended to provide adequate reimbursement to a pharmacist for the cost of dispensing prescriptions and a reasonable profit, it is no longer as distinct from drug cost reimbursement as it once was, or as it should be. There has been a growing tendency, supported by fee adjustments, for pharmacy reimbursement to be viewed as a total revenue package which must be maintained at a certain level, rather than as being composed of two separate elements--drug cost and dispensing fee. In the Commission's view, for the drug cost plus fee concept to work well, this tendency must be checked. Unless pharmacies and payers return to considering these two components separately, and to defining them specifically, the potential for inequities to develop will increase.

The Commission recommends, therefore, that:

1. the Ministry of Health and the Ontario Pharmacists' Association continue to negotiate a single dispensing fee, and use objective information on dispensary cost elements to assist in determining the amount of the fee. The negotiated dispensing fee should continue to be applicable to all Drug Benefit prescriptions with the exception of over-the-counter products, and to all PARCOST pharmacies;

2. the Ministry of Health should work with the Ontario Pharmacists' Association and other organisations representing pharmacy to define precisely the cost elements of which the negotiated dispensing fee is composed, and should collect sufficient information from representative Ontario pharmacies to identify the nature of those costs (fixed or variable with dispensing volume), the factors influencing these costs, and trends in the level of these costs across pharmacies and over time (Appendix F). The purpose of this recommendation is threefold:

    i) to emphasise the specific purpose of the fee, and to separate it clearly from drug

cost reimbursement;

ii) to provide sufficient information to service providers and payers to enable them to conduct fee negotiations using a mutually established body of data as is done in the United Kingdom;

iii) to provide the Ministry of Health with information about differences in pharmacy operating costs with respect to location, size, and proportion of third-party dispensary business; this can be used as the basis for instituting subsidies to some or all pharmacies for specific reasons, such as supporting certain classes of pharmacies and ensuring strong service delivery in rural areas;

3. the dispensing fee not be adjusted when the basis for determining prices is changed. Such fee adjustments only serve to erode the usefulness of the cost plus fee concept. The most recent adjustment of $0.35 should not be considered as being caused by a change in listed prices, but should be included in the base for fee negotiations. This base fee of $5.00 appears to be equitable when compared to negotiated fees in other provinces, and the Commission believes that future fee negotiations will be greatly assisted by the collection of more precise information on dispensary costs.

SECTION 155

The use of interchangeable drug products is one of the chief methods by which pharmacies can contribute to the control of reimbursement costs within the present system. Given the importance of this method, the Commission gave careful consideration to the therapeutic, legal, and economic aspects of interchangeability, the latter, of course, depending on the former two for its existence.

With respect to the therapeutic soundness of designating certain drug products as interchangeable, the Commission notes that the work of the Drug Quality and Therapeutics Committee has been quite satisfactory in evaluating such products. At the same time, interchangeability remains a

source of some concern in the medical community. The Commission would like to stress, therefore, that it is important that the methods for determining interchangeability keep pace with advances in knowledge about the potential for problems created by the substitution or selection of interchangeable products.

The legal aspect of interchangeability, that is, the ability of the provincial government to protect prescribers and pharmacists from civil litigation arising from any injurious acts caused by product selection or substitution, is much less of a matter for concern in that, although the legislation has never been tested, it appears to fulfill its purpose [Appendix G].

Finally, with respect to the economic aspect of drug product interchangeability, the Commission recommends that:

1. Section 155 of the Health Disciplines Act be amended to allow pharmacies to charge a usual and customary fee when product substituting or product selecting. The Commission believes this amendment will remove the strongest barrier to the increased use of interchangeable products in the present system;

2. Section 155 be amended to delete the phrase "at a price in excess of the cost of the lowest priced interchangeable pharmaceutical product in his inventory" as it applies to product substitution. Pharmacies should continue to be restricted to the lowest price in inventory on product selected prescriptions. These amendments should moderate any enforcement problems caused by the lowest in inventory rule, and act to preserve the economic advantage enjoyed by consumers when selection or substitution is practised, particularly if consumer awareness of dispensing fees is increased as proposed in the secondary recommendations;

3. the Ministry of Health and pharmacy organisations should set a target level of substitution to be achieved, and

the Ministry of Health and the Ontario College of Pharmacists should monitor the level of product substitution achieved within a reasonable time following this amendment. If the response on the part of pharmacists is not satisfactory, the Ministry should take stronger measures to increase substitution, such as instituting mandatory price substitution in the non-Drug Benefit market.

VI.B. SECONDARY RECOMMENDATIONS

The following secondary recommendations address three broad areas of concern raised in the submissions received by the Commission. These are the need for more and better market information; the need to clarify the meaning and the components of the dispensing fee; and the need to control prescription reimbursement costs. Recommendations put forward in each of these areas are, for the most part, not specific, but are intended instead to identify types of activities which could usefully be undertaken to improve the operation of Ontario's retail prescription market.

INFORMATION

As has already been noted, the amount of information available to all participants is either insufficient or is not used well. The Commission recommends, therefore, that:

1. the Ministry of Health should seek the co-operation of pharmacists and manufacturers in carrying out a continuous and consultative process of collecting information on activites in the retail prescription market. Information should be gathered in such areas as prescription prices in other provinces, dispensary costs, wholesale drug prices, trends in the practice of product substitution and generic prescribing, price trends of single-source products, prices paid by hospital dispensaries in purchasing drug products, and the effectiveness of activities in other jurisdictions, such as the capitation trial in British Columbia. The Ministry of Health should consider establishing an advisory committee representing the four principal parties which would have the responsibility for determining the scope and methods used for this monitoring activity. The four principal parties, and other organisations representing pharmacy and manufacturers, should be fully informed of the types of information being collected, and the information collected should be available to all parties;

2. the Ministry of Health should contract with an independent market research firm to conduct a continuous consumer panel on health services in Ontario. Preceded by a pilot study, the panel would be composed of a representative group of people, and would yield quantitative information as to the levels of consumption of and interrelationships among hospital, nursing home, physician, and pharmaceutical services. This information could then be used to analyse patterns of consumption, changes in those patterns, and the causes of such changes;

3. the Ministry of Health should amend the regulations under the Pharmacy Part of the Health Disciplines Act either to allow or to make mandatory the posting of dispensing fee information and the inclusion on prescription labels of a breakdown of the total prescription price into its two components of drug cost and dispensing fee. The former, more permissive, approach to providing consumers with this information is preferred; however, it can only work with the support of the Ontario College of Pharmacists and other organisations representing pharmacies. If such support is not forthcoming, the mandatory approach should be used;

4. finally, the Ministry of Health should consider restructuring Ontario Drug Benefit in such a way as to encourage beneficiaries to act on its behalf as cost control agents. This could be done by instituting either a co-payment system whereby the beneficiary pays the pharmacist either a fixed dollar or fixed percentage amount each time a prescription is filled; or a co-insurance system whereby the beneficiary is responsible for the purchase of all prescriptions up to a deductible limit and eligible for a fixed percentage reimbursement on all prescriptions thereafter; or by a system under which beneficiaries pay for their prescriptions and receive full reimbursement directly from the Ministry of Health. Any one of these approaches would provide a mechanism for increasing the cost consciousness of consumers, and, therefore, encouraging some competition at the retail level.

DISPENSING FEE

The cost plus fee concept for reimbursing pharmacy has now been used for nearly two decades. While some doubts are beginning to be expressed

about its continued usefulness, particularly with respect to high-cost drug therapies, the Commission believes the present concept is the best available, and is flexible enough to respond to changing dispensary conditions. The Commission recommends, therefore, that:

1. in conjunction with fee posting, the Ministry of Health co-operate with the Ontario College of Pharmacists and all organizations representing pharmacies to promote to the public the professional nature of the services provided by pharmacy. Consumer education in this area could include such items as the professional health-care advice available from pharmacists, and their extensive knowledge of appropriate drug therapy.

2. the Ministry of Health, because of technology improvements, now has the ability to move to a full payment system. By doing so, it could do much to remove an aspect of Drug Benefit which appears to cause unnecessary friction between it and pharmacy.

REIMBURSEMENT COST CONTROL

The control of prescription reimbursement costs is central to the continuation of drug reimbursement programmes as we know them. As long as the drug cost plus fee concept is used for pharmacy reimbursement, service providers and payers will continue to be engaged in two important activities: first, finding a definition of drug cost which is fair to both parties in the face of a dynamic marketplace; and, second, looking for indirect ways to control drug costs at no sacrifice to the level of therapy available. With respect to the former activity, the Commission recommends that:

1. the Ministry of Health use, whenever possible, its dominant position in the Ontario retail prescription market to influence drug costs at either the retail level or the manufacturers' level or both. As a major

buyer of pharmacy services and pharmaceutical products, and as the trustee of public funds, the Ministry has the ability and the responsibility to take action, whether through a standing offer contract system or through extensive monitoring of wholesalers' and manufacturers' price lists in Ontario and elsewhere and informal negotiation with manufacturers and pharmacists to ensure reimbursement prices are realistic;

2. the Ministry of Health should engage in more frequent dialogue with manufacturers, both generic and patent-holding, in order to improve its working relationship with them, and to increase opportunities for resolving concerns and sharing information about pricing and marketing practices, and about the impact of provincial programmes on the manufacturers.

With respect to activities aimed at exercising a more indirect form of control over reimbursement costs, the Commission recommends that:

1. the Ministry of Health work in co-operation with pharmacy and physician representative bodies to explore and implement procedures for reducing waste of prescription drugs by encouraging more rational prescribing and dispensing practices, such as the use of drug utilisation review committees, and the use of trial prescriptions; as well, as a means of moderating the need for health care services overall, these parties should consider conducting public education programmes promoting healthy lifestyles by educating the public about the relationship of lifestyle to health;

2. the Ministry of Health and the Ontario Pharmacists' Association should agree to delete Paragraph 5 of the Participation Agreement and return to the practice of "dispense as written" for Ontario Drug Benefit recipients. In the Commission's view, this subsidy to pharmacy does not yield benefits commensurate with its costs; rather, if the Ministry and the Ontario Pharmacists' Association agree that some form of subsidy can be justified, that subsidy should be derived from a quantitatively sound body of information, and should reflect some clearly defined policy goal;

3. the Ministry of Health encourage the Ontario Medical Association to educate its members about the benefits of generic prescribing and the use of lower-cost drug products from generic manufacturers. To date, the patent-holding manufacturers have been the most active

group in educating physicians about new drug therapies. The Commission believes that physicians can perform a key role in controlling drug costs and, therefore, total health care costs. The Commission also believes that physicians should do so in the interests of ensuring that the level of funding of prescription services does not increase to such an extent that funding for other health services is harmed. The O.M.A., through its educational activities, is the appropriate body to provide physicians with the information and guidelines necessary for them to participate in cost control activities.

VII. CONCLUSION

The Commission believes that the two preceding sets of recommendations provide the four principal parties with a sound basis for improving the present structure of Ontario's prescription drug policies and programmes, and for improving their relationships within this structure. The Commission would like to urge the Ministry of Health to try to ensure that not only are its policies and programmes consistent in their goals but also that they are applied consistently to all participants and at all times. It is the responsibility of the Ministry, as the author and operator of its programmes, to do so in order to avoid not only the types of problems which may arise in the day-to-day functioning of any system, but also the types of problems which can arise when good programmes are applied and enforced poorly. The Ministry's role can be seen as one of leadership--it must provide all parties with a fair framework within which to operate, and it must be prepared to ensure that its programmes and policies are respected, and worthy of respect.

Finally, the Commission would like to remind the four principal parties that without good will, consultation and co-operation, no system will work satisfactorily for long. The cycle of seeking recommendations and then not heeding them, whether for reasons of excessive caution or intransigence, is a cycle which must end. It is vitally important that the parties put aside old attitudes and grievances and work toward making the present system operate as well and as fairly as it can, for themselves, certainly, but ultimately for the citizens of Ontario.

APPENDIX A

PRICE-ADJUSTED DRUG PRODUCTS

I. February 1979 List of Bailey Drugs

Tetracycline 250 mg Cap
Digoxin 0.25 mg Tab
Digoxin 0.125 mg Tab
Propranolol 40 mg Tab
Propranolol 10 mg Tab
Methyldopa 250 mg Tab
Hydrochlorothiazide & Spironolactone 25 mg & 25 mg Tab
Hydrochlorothiazide & Triamterene 25 mg & 50 mg Tab
Isosorbide Dinitrate 5 mg SL Tab (100)
Isosorbide Dinitrate 10 mg Tab
Acetaminophen 325 mg Tab
Acetylsalicylic Acid 650 mg Tab
Acetylsalicylic Acid 325 mg Tab
Ibuprofen 200 mg Tab
Indomethacin 25 mg Cap
Phenylbutazone 100 mg Tab
Propoxyphene Cap
Ibuprofen 300 mg Tab
Naproxen 250 mg Tab
Phenytoin 100 mg Tab
Amitriptyline 25 mg Tab
Chlordiazepoxide 10 Cap
Diazepam 10 mg Tab
Diazepam 5 mg Tab
Diazepam 2 mg Tab
Flurazepam 30 mg Cap
Potassium Chloride 8mEq LA Tab
Furosemide 40 mg Tab
Hydrochlorothiazide 50 mg Tab
Hydrochlorothiazide 25 mg Tab
Spironolactone 25 mg Tab
Sulfinpyrazone 200 mg Tab
Prednisone 5 mg Tab
Chlorpropamide 250 mg Tab
Tolbutamide 500 mg Tab
Oxytriphylline 200 mg Tab

II. Drug Products for Which Prices Were Adjusted
February 1984

Prices adjusted on a 1000's basis:

1. ASA enteric 650 mg
2. Amitriptyline 25 mg
3. Chlordiazepoxide 10 mg
4. Chlorpropamide 250 mg
5. Cimetidine 300 mg
6. Diazepam 5 mg
7. Flurazepam 30 mg
8. Furosemide 40 mg
9. Hydrochlorothiazide 50 mg
10. Hydrochlorothiazide/Triamterene 25/50 mg
11. Isosorbide Dinitrate 30 mg
12. Isosorbide Dinitrate 10 mg
13. Methyldopa 250 mg
14. Methyldopa/Hydrochlorothiazide 250/25 mg
15. Naproxyn 250 mg
16. Oxazepam 15 mg
17. Oxtriphylline 200 mg
18. Propranolol 40 mg
19. Propranolol 10 mg
20. Sulfinpyrazone 200 mg

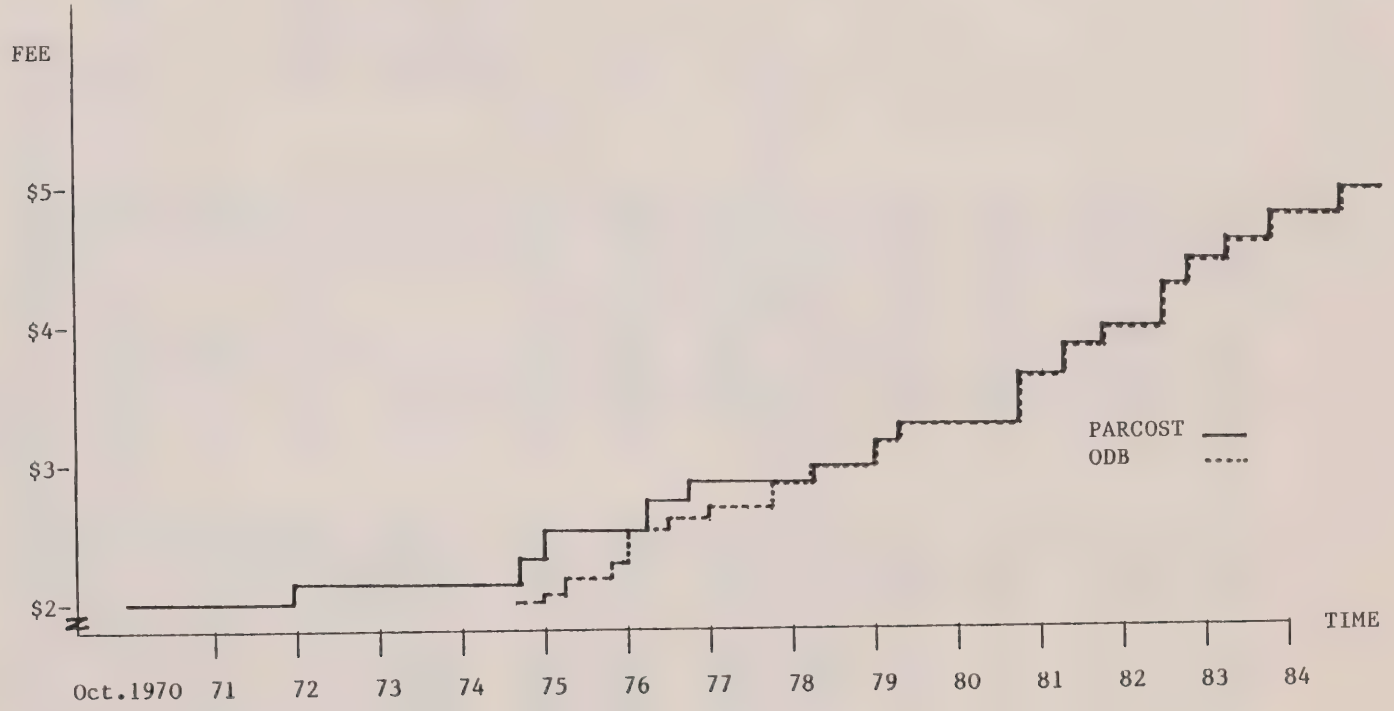
Prices adjusted on 100's basis:

1. Allopurinol 300 mg
2. Allopurinol 100 mg
3. Chlorthalidone 50 mg
4. Furosemide 20 mg
5. Imipramine 25 mg
6. Methyldopa 500 mg
7. Oxazepam 30 mg
8. Propranolol 80 mg
9. Sulfamethoxazole/Trimethoprim 400/80 mg
10. Sulfinpyrazone 100 mg

APPENDIX B

COMPARISON OF MAXIMUM DISPENSING FEE

PARCOST AND ODB



COMPARISON OF MAXIMUM PRESCRIPTION DISPENSING FEE

PARCOST AND ODB

YEAR	PARCOST	ODB
Oct. 1970	$2.00	Not yet in operation
1971	$2.00	Not yet in operation
1972	$2.20	Not yet in operation
1973	$2.20	Not yet in operation
Sept. 1974	$2.40	$2.05
Jan-March 1975	$2.60	$2.10
Apr-Dec. 1975	$2.60	$2.25*
Nov-Dec Jan-March 1976	$2.60	$2.60 (Jan-June)
Apr-Sept. 1976	$2.75	$2.65 (Jul-Dec.)
Oct-Dec. 1976	$2.85	
1977	$2.85 $2.85 (Oct-Dec.)	$2.70 (Jan-Sept) $2.85 (Oct-Dec.)
1978	$2.85 (Jan-Mar.) $2.95 (Apr-Dec.)	$2.85 (Jan-Mar.) $2.95 (Apr-Dec.)
1979	$3.17 (Jan-Mar.) $3.27 (Apr-Dec.)	$3.17 (Jan-Mar.) $3.27 (Apr-Dec.)
1980	$3.27 (Jan-Sept) $3.65 (Oct-Dec.)	$3.27 (Jan-Sept) $3.65 (Oct-Dec.)
1981	$3.65 (Jan-Mar.) $3.90 (Apr-Sept) $4.00 (Oct-Dec.)	$3.65 (Jan-Mar.) $3.90 (Apr-Sept) $4.00 (Oct-Dec.)
1982	$4.00 (Jan-July) $4.37 (Aug-Sept) $4.48 (Oct-Dec.)	$4.00 (Jan-July) $4.37 (Aug-Sept) $4.48 (Oct-Dec.)
1983	$4.48 (Jan-Mar.) $4.55 (Apr-Sept) $4.65 (Oct-Dec.)	$4.48 (Jan-Mar.) $4.55 (Apr-Sept) $4.65 (Oct-Dec.)
1984	$4.65 (January) $5.00 (Feb-Present)	$4.65 (January) $5.00 (Feb-Present)

*$2.37 Nov-Dec (1975)

APPENDIX C

PROFILE OF THE RETAIL PRESCRIPTION MARKET IN ONTARIO 1983-84*

	NON-DRUG BENEFIT	ONTARIO DRUG BENEFIT
Number of people	7,700,000	1,300,000
% of population	86%	14%
Number of prescriptions	30,000,000	25,000,000*
% of total prescriptions	55%	45%
Prescriptions/person	4.28	19.2
Dispensing fee/prescription	$5.35	$5.00
Total fee revenue	$160,500,000	$125,000,000*
% of total fee revenue	56%	44%
Fee revenue/person	$20.84	$96.15

*The figures marked by an asterisk in this Appendix are from the Ministry of Health, and were confirmed by information provided in other submissions. The remainder are simply the result of the indicated calculations.

APPENDIX D

The results of an informal price comparison which the Commission conducted across Canada are presented in the following tables. Given the wide variations in programmes from province to province, this comparison is not intended to provide conclusive results about relative prescription prices. The intent, rather, was to demonstrate the differences in total prescription prices that arise, to a greater or lesser degree from the differences in prescription drug policies and programmes used by the various provinces. The results, therefore, should only be interpreted with a great deal of caution and with full knowledge of the details of each province's programme.

The prescriptions in the following tables were priced according to these qualifications:

1. The prescription is for a specific drug product and "no substitution" is marked in the prescriber's handwriting. Although we acknowledge that this type of prescription is atypical, we felt it was a necessary control to facilitate a price comparison among provinces.

2. Each product, in a package of 100, is being dispensed for a 34-day supply.

3. Where a province has a graduated fee schedule, the highest fee was paid.

Drug Entity / Fee	British Columbia	Manitoba	Newfoundland	New Brunswick	Nova Scotia	Ontario	Quebec	Saskatchewan
Fee	5.90	5.05	5.25	5.55	5.50	5.00	3.62	5.30
*Deltasone 5 mg	1.50	2.39	NI	NI	2.39	2.39	2.60(30)	2.65
*HydroDiuril 50 mg	4.80	6.82	7.04	7.49	6.62	6.62	7.36(50)	7.71
Ilosone 250 mg cap	NI	28.49	NI	NI	29.90	27.41	27.97(30)	22.08**
*Inderal 40 mg	7.57	11.74	11.73	NI	8.50	14.08	8.82^	15.54
*Lasix 40 mg	5.96	6.48	6.47	6.48	6.48	7.12	7.06(50)	7.20
Novocloxin 250 mg cap	NI	9.29	14.04	15.18	9.04	12.65	13.30(30)	6.60**
*Novotetra 250 mg	2.16	2.46	4.56	6.43	4.58	4.80	5.44(30)	2.10**
Stabinol 250 mg	NI	4.76	6.05	6.05	6.05	4.76	4.76(100)	6.16
Tagamet 300 mg	15.82	26.79	27.74(1000)	NI	27.27	26.54	15.00^(100)	28.19
*Valium 10 mg	NI	11.90	15.98	13.90	16.68	13.09	15.16(50)	15.43

Notes

* - Bailey Drug - Ontario high volume drug
** - SOC - Saskatchewan high volume drug
(50) - These numbers indicate the package size that the prices are based on
^ - PRA - Quebec high volume drug
NI - Product not included in formulary or price list
Fee - The maximum provincial dispensing fee for each province
- In the case of British Columbia, the fee represents the provincial average fee
Ingredient Cost - These are maximum prices for all provinces except British Columbia, where figures represent average prices. The prices for New Brunswick and Nova Scotia were taken from the January 1984 Formularies,
PEI, Alberta - These provinces were not included in the survey as they do not publish formularies and other sources of pricing information were not available.
British Columbia - Source of prices was an end of year 1983, price list provided by B.C. Pharmacare.

TOTAL PRESCRIPTION PRICE

Drug Entity / Fee	British Columbia	Manitoba	Newfoundland	New Brunswick	Nova Scotia	Ontario	Quebec	Saskatchewan
	5.90	5.05	5.25	5.55	5.50	5.00	3.62	5.30
*Deltasone 5 mg	7.40	7.44	NI	NI	7.89	7.39	6.22(30)	7.95
*HydroDiuril 50 mg	10.70	11.87	12.29	13.04	12.12	11.62	10.98(50)	13.01
Ilosone 250 mg cap	NI	33.54	NI	NI	35.40	32.41	31.59(30)	27.38**
*Inderal 40 mg	13.47	16.79	16.98	NI	14.00	19.08	12.44^	20.84
*Lasix 40 mg	11.86	11.53	11.72	12.03	11.98	12.12	10.68(50)	12.50
Novocloxin 250 mg cap	NI	14.34	19.29	20.73	16.54	17.65	16.92(30)	11.90**
*Novotetra 250 mg	8.06	7.51	9.81	11.98	10.08	9.80	9.06(30)	7.40**
Stabinol 250 mg	NI	9.81	11.30	11.60	11.55	9.76	8.38(100)	7.93
Tagamet 300 mg	21.72	31.84	32.99	NI	32.77	31.54	18.62^ (100)	33.49
*Valium 10 mg	NI	16.95	21.23	19.45	22.18	18.09	18.78(50)	20.73

APPENDIX E

For Dean J.R.M. Gordon
Commissioner - Ontario Drug Inquiry

Pricing and Distribution of Drugs in the United Kingdom

Kristian S. Palda
June 1984

Preface

This brief description and discussion is based on a conversation with Mr. L.T. Wilson, Administrator for Pharmaceutical Services Part 2, Dept. of Health and Social Security (DHSS), Hannibal House, Elephant and Castle, London SE 1, and on the printed material he kindly supplied.

The NHS and drugs

Like most other national health systems the British National Health Service (NHS) underwrites the cost of hospital care, physician services and, to a large extent, patient outlays for drugs. In fiscal 1980-81 the cost of drugs prescribed by general practitioners was £866 million, the amount spent by hospitals £185 million, and fees and other allowances to pharmacists reached £234 million, for a total of £1,285, or about 10 percent of the total outlays of the NHS.

While hospital and physician services are completely gratis, there is a prescription fee of (currently) £1.60 to be paid by patients to pharmacists. There are, however, so many people exempt from this fee -- under 16, over 65, the unemployed, the pregnant, the chronically ill,

etc. — that about 70% of prescriptions are filled free of charge.

Unlike France, there are no special categories of drugs benefitting or not benefitting from subsidy: any prescription by a physician is eligible for standard treatment, whether antibiotics or headache remedies. Given that some medicines may cost less than £1.60, it pays the non-exempt patients to buy OTC drugs without a prescription. This is one of the reasons why of late the Pharmacists' Association of Great Britain is backing a publicity campaign addressed to the general public on the theme "Ask your pharmacist." The potential benefit to the patient (no prescription fee), to the pharmacist (no official form processing charge, no markup restriction) and to the NHS (no physician cost) are obvious.

Pricing and reimbursement mechanics

a) Pharmaceutical manufacturers

Every year, under the current, voluntarily agreed Pharmaceutical Price Regulation Scheme (PPRS), the Dept. of Health (DHSS) determines indirectly the general price level of domestically produced drug products at the wholesale level. The adjective "indirectly" is used deliberately: DHSS, presumably after consultation with the industry association, sets a target rate of return on investment for the industry as a whole which should not be exceeded. In negotiations with individual companies a specific target ROI is set given some reference to the industry's ROI. The prices of the individual drugs each company is selling are at its discretion, as long as its own target ROI is not exceeded. (The

exception is a direct approval by DHSS of price increases for NHS products with large home sales). Naturally, DHSS monitors each company's costs, in particular those of R & D and of sales promotion, the latter generally limited to 10% of sales.

This pricing scheme is based on two governmental objectives: the first is to secure the availability of safe and effective medicines on fair and reasonable terms to the NHS, while an important secondary objective is to promote a strong, efficient and profitable pharmaceutical industry in the UK, capable of supplying new and improved medicines to the NHS and for export.

Finally it should be mentioned that the list prices which emerge under the PPRScheme are truly wholesale prices, those which the pharmacist pays; they already incorporate the wholesaler's margin of gross profit.

b) Pharmacists

It is perhaps best to view the pharmacists as being remunerated for their work for NHS: they are reimbursed for the wholesale cost of drugs, they get an "on-cost" allowance, they receive a professional fee per prescription and they are given an annual basic practice allowance. Of course, the pharmacists are also independent business people and sell in their chemist's shops items unrelated to NHS.

1. In greater detail, the reimbursement of the wholesale cost of drugs and appliances is based on the official price list, the Drug Tariff (a red booklet issued every year by DHSS). Since the wholesalers usually offer quantity discounts to the pharmacists, the reimbursement scheme takes this into account by applying discounts as well: 0.7 percent where the monthly cost of prescriptions exceeds £1,000 to 6.4 percent where it exceeds £12,000.

2. A container allowance of 3.8 pence per prescription.

3. A professional fee per prescription averaging 40 pence, but varying in accordance with the Drug Tariff.

4. A basic practice allowance of £2,400 a year to pharmacies in business before July 1, 1980 and to new pharmacies which did not locate closer than 1 kilometre to an existing pharmacy.

5. An "on-cost" allowance on the wholesale cost of drugs dispensed. The highest rate (26 percent) is paid where the least number of prescriptions was dispensed (1 to 249 prescriptions per month), the lowest rate (9 percent) is paid where the highest number of prescriptions was filled (over 5,000 per month).

This on-cost allowance is the subject of protracted negotiations between DHSS and the Pharmaceutical Services Negotiating Committee, representing the pharmacists, every year. The pharmacies' labour and other costs are periodically ascertained by surveys of a representative sample of pharmacies.

6. Additional payments to small rural pharmacies for providing essential services, etc.

As can be observed, this pricing and distribution system gives little scope to the individual pharmacist or to drug chains for profit-oriented pricing. Drug manufacturers would have difficulty persuading the chemist retailers to favour their products since the prescription fee in a therapeutical class is uniform and, above all, since the pharmacist cannot substitute one equivalent drug for another.

A final note: it is estimated that pharmacists and the NHS process about 330 million prescription forms annually. (All the above figures refer to 1983).

Current developments

The British government is able to impose annual cash limits only on the hospital component of the NHS; physician and drug expenses are to

some extent open-ended.

It is of interest that in NHS hospitals 60 percent of all prescriptions are to generic drugs. General practitioners, it is estimated, write 15 percent of their prescriptions on such drugs, but only to 5 percent of the monetary value of total prescriptions. However, even here the share of generics is rising.

General practitioners can get, on request, a statistical summary of their prescribing habits from the so-called Prescription Pricing Authority and may be called upon by their medical association to justify "excessive" drug prescriptions. An incipient computerization of prescription form processing should give the physician quick access to a detailed overview of his prescriptions.

During the last two years some wholesalers have been importing from Common Market countries drugs either exported there by British manufacturers at much lower than domestic prices or manufactured there by a sister branch of a British manufacturer. The pharmacists were then offered these so-called "parallel imports" at much lower prices by the wholesalers, yet were being reimbursed at the official, higher domestic Drug Tariff rate. The Economist (March 24, 1984, pp. 56-57) estimated the retail value of these sales at between 30 - 100 million pounds. The Dept. of Health was not fundamentally opposed as long as it could detect the transactions and reimburse at the lower import cost. However, it gave in to the pressure by the Association of British Pharmaceutical Industry and appears to be blocking these parallel imports by way of requiring regulatory approval to so-called British standards

(U.K. Hansard, May 16, 1984, p. 158).

Future perspectives

In the opinion of Mr. Wilson, the DHSS official, two future developments that are susceptible to limit the rising cost of drugs to the NHS are on the horizon. The first is a determined move to substitution: doctors made more aware of lower-priced substitutes, pharmacists given some leeway, etc.

The second development of broad scope would be a "rationalization" of the retail, pharmacy end of the drug circuit. Envisaged might be a limit on the number of pharmacies, a simplification of the reporting procedure, a shortening of the negotiations between the DHSS and the pharmacists' association, etc.

Final remarks

Missing from this report is an appreciation of the change in the share of drug costs in total NHS outlays which would provide an overall perspective on the behaviour of health costs. This may be supplied shortly by DHSS.

There is also no appreciation of the relative shares of the NHS and private-sector business in a typical UK pharmacy and therefore of the extent to which pharmacists are beholden to the state.

APPENDIX F

DISPENSING FEE COST ELEMENTS

The following list of the cost elements associated with dispensary operations has been compiled from four sources--the Canadian Pharmaceutical Association annual survey of community pharmacy operations, the Uniform Cost Accounting System, Green Shield Prepaid Services, Inc., and Lilly Digest. It is intended to be a guide to the type of information the Ministry of Health and the Ontario Pharmacists' Association should collect in order to improve the negotiation of the Drug Benefit and PARCOST dispensing fees. As well, a list of the factors which may account for variability in the costs of dispensing from one class of pharmacy to another is included to suggest possible foundations for any future subsidies paid to pharmacies.

1. Proprietor's Salary
2. Employee Wages
3. Occupancy (Rent, Utilities)
4. Taxes and licenses
5. Interest Paid
6. Advertising
7. Depreciation (Fixtures)
8. Insurance
9. Accounting, legal and other professional services
10. Delivery*
11. Supplies (labels, bottles)
12. Equipment Repair
13. Dues/Memberships, seminars, subscriptions, books
14. Telephone (communications)
15. Bad Debts Charged Off
16. Spoiled Medication or obsolescence
17. Miscellaneous
    - Travel
    - Freight Charges
    - Professional Attire
    - Equipment Rental
    - Prescription Files
18. General Administration allocated to Prescription Department
19. Return on Assets

*There is some discussion as to whether this is to be considered an expense.

FACTORS WHICH MAY CONTRIBUTE TO THE VARIABILITY OF DISPENSARY COST ELEMENTS

Factors	Description
ownership	Chain vs. independent
geography	rural vs. urban vs. suburban
location	mall vs. street
size	volume
clientele	direct vs. third party
market	front vs. back shop
services	hours of operation

APPENDIX G

Report on Legal Issues Associated with Section 155 of the Health Disciplines Act

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I. Our principal task is to construe S.155(4) of the Health Discipline Act[1] and determine how it applies to the classes of people and prescription drug sales discussed in S.155(1-3).

Application of S.155(4) to Persons

Subsection 4 applies to prescribers or pharmacists. The "or" is interpreted inclusively so that both classes of people are covered by this subsection simultaneously. The word prescribers is defined in S.113(1)(1) of the Act. The definition includes doctors, dentists, and any other health-care professionals who are authorized within their practice to prescribe drugs to their patients. The word pharmacist, defined in S113(1)(j), means anyone licensed by the Act to practice pharmacy and sell drugs to the public.

Application of S.155(4) to Sales Transactions

Subsection 4 refers to the sale of "interchangeable pharmaceutical product(s) other than the one prescribed", where such sales are "in accordance with this section" (155). The phrase interchangeable pharmaceutical product is defined in S.113(1)(e). It refers to a product containing the same active ingredient in the same amount and in the same dosage form as that directed by a prescription. The word "prescription", and the phrases "drug prescribed", and "pharmaceutical product prescribed" are ambiguous. They could refer only to open prescriptions, in which case S.S.4 should only apply to subsections 1 and 3. They could refer to both open and generic prescriptions, in which case it could be argued that the entire section is affected by subsection 4.

If subsection 4 was meant to apply only to subsections 1 and 3, the phrase "in accordance with this section" should have read "in accordance with subsection 1 and 3", assuming the legislators thought about this question of interpretation. It seems reasonable to assume that the legislators did advert to the question and used the more general qualification of sales transactions with the intent of including the generic prescriptions dealt with in subsection 2 within the scope of subsection 4.

Thus the transactions referred to in subsection 4 are limited to those initiated by either an open or a generic prescription and done in accordance with the conditions set out for such transactions in subsections 1, 2 and 3. For such transactions, the prescriber or the pharmacist receives some as yet undefined protection from legal action if the transaction is carried out in accordance with the imposed conditions.

The lack of a no substitution order on a prescription is treated as one of the conditions for discretionary substitution to be within the scope of subsection 4. This implies that a no-substitution prescription does not come within this scope, which appears to be a conscious decision of the legislators. The legislators discussed particular types of prescriptions and sales transactions in this section rather than a more general case. The particular cases not mentioned exist at the same level of abstraction as those included in the section, which suggests that the drafters of the legislation thought about all such particular cases and omitted those from discussion that were not to be included in the scope of subsection 4. Similarly, any other cases not mentioned are excluded. The excluded cases are governed by the appropriate law of contract, tort, or by the Sale of Goods Act, which leaves open to individual action the question of liability of pharmacists and prescribers.

Scope of protection afforded by S.S. 155(4)

Subsection 155(4) of the Act bars an action or other proceeding for various reasons to be discussed. The word action can only refer to civil action and not criminal. The Province of Ontario has the power to pass legislation that regulates the exercise of civil rights, at least so long as the legislation does not abrogate such right. Here the denial of a right to civil action is intra vires the constitutional powers of the Province so long as other solvent parties can be subject to similar civil action. If for no other reason, this suggests that the Province may be subject to such action. The other proceeding referred to may mean a proceeding of a professional organization against one of its members, or some other proceeding before an administrative tribunal.

The action barred must be grounded on the fact that an interchangeable pharmaceutical product other than the one prescribed to a patient was sold to a patient, and some injury results from this fact. As we concluded above, this premise fact may arise when a prescriber prescribes a drug product by its brand name (open prescription) and a pharmacist decides to sell the patient an interchangeable drug product from another manufacturer. This we call a discretionary drug substitution. Here, there is a clear distinction between what drug manufacturer the prescriber had in mind when the prescription was written and the manufacturer of the product the patient receives at sale. It makes sense to imagine that this change could result in an injury to the patient that would not have occurred without the change.

We also concluded for purely linguistic reasons that the premise fact may arise when a prescriber uses a generic prescription (the manufacturer is not specified) and a pharmacist must select a drug in this interchangeable class that is listed in the Parcost C.D.I. and satisfies other cost conditions. This we can call a mandatory drug selection. There are jurisprudential as well as linguistic reasons to bar civil action for mandatory drug selection. To show this, let us assume the opposite. What result obtains? To protect pharmacists from liability for discretionary substitution of interchangeable products and not mandatory selection of interchangeable products supports the general proposition that the degree of one's real and legal responsibility for the consequences of one's actions are inversely related, or that states should be disposed to impose greater liability for non-discretionary wrongs than discretionary ones. Such propositions are contrary to the most elementary doctrines of law and to basic common sense. We cannot allow civil action for mandatory drug selection without looking like fools.

However, with mandatory drug selection, it is harder to distinguish between what the prescriber had in mind when the prescription was written and what the patient receives at sale. What the prescriber had in mind was not brand-specific. The prescriber only indicates the active ingredient, strength and dosage form. The pharmacist's choice crystalizes that idea to be brand-specific. In one sense what was sold was what was prescribed, if we consider a generic prescription as being satisfied by one of several interchangeable drugs. This interpretation of 'drug prescribed' would leave subsection 2 out of the scope of subsection 4 and allow civil suits for mandatory drug selection But we don't like that result for other reasons, so we must dig for other interpretations to support our worthy conclusion.

For there to be a distinction between what is prescribed and what is sold a change must have occurred that could result in an injury to the patient that would not have occurred without the change; otherwise why bar a potential cause of action for this injury? There is an implicit patient expectation to such an action that either the pharmacist or the prescriber should have made a different choice. Perhaps the pharmacist should have called the prescriber to request a more specific prescription. Perhaps the doctor should have been more specific or should have made no prescription at all. It is not difficult to imagine actions that could have reduced or eliminated the impact of the change associated with generic prescribing and mandatory selection. The Province, for reasons of public policy, has decided to encourage generic prescribing and mandatory selection of prescription drugs by protecting prescribers and pharmacists from civil action for not doing otherwise when there may be reasons to do so. The reason we seek to justify our conclusion to include subsection 2 within the scope of subsection 4 is that, by doing so, the taxpayers as a whole should save money. The people who have lost the opportunity for such civil action, it would be argued, will not be harmed if there remain solvent alternative parties who can be sued successfully to compensate them.

The danger behind such a policy is that, unlike the discretionary substitution case, we do not know what potentially wrongful omissions the legislation is designed to shield from civil action. The pharmacist can avoid the effect of discretionary substitution by selling the patient the drug prescribed. The prescriber can avoid the effect of discretionary substitution by stipulating 'no substitution' on the prescription. Subsection 4 shields both parties from civil liability for not avoiding substitution, and observers can easily assess whether the benefit society enjoys from this rule is worth the price. The effect of mandatory drug selection vis a vis pharmacists and prescribers is more vague and so are the means for reducing it. Does the legislation, for example, protect the prescriber from liability for prescribing a drug when he/she should not have? Clearly this protection is contrary to public policy and sound medical practice. But try another example. Does the legislation protect the prescriber from a failure to become knowledgeable about the side-effects of a specific brand of drug product and to use more 'no substitution' prescriptions to reduce the incidence of side-effects? Here reasons of public policy and medical ethics perhaps conflict, and we have no readily available means of assessing the trade-off to clarify the necessary scope of the legislation.

Thus I would expect that if patients were to bring actions against prescribers or pharmacists for their actions under S.155 of the Health Disciplines Act, they will seek to limit the scope of subsection 4 as applied to subsection 2.

II. A second task is to assess the potential liability of other parties for the injurious consequences of discretionary drug substitution and mandatory drug selection. The Province of Ontario must automatically be considered potentially liable as the party of last resort in civil litigation to make the legislation intra vires the constitution.

If section 92(13) of the Constitution is interpreted as requiring Provincial regulation of property and civil rights associated with prescription drug manufacture, sale and distribution, then there is ample case law to support the proposition that the Province would also be liable in tort for the negligent performance of its duty to inspect.[2] If the province had no statutory obligation to inspect and assess the interchangeability of prescription drugs, it would still be liable in tort for any injuries to persons resulting from a reasonable reliance on any negligent statements provided without conditions by the province about the interchangeability of various drug therapies.[3] And, because the general public has no real choice but to accept the Province's evaluation, the case for Provincial compensation of those hurt by their reliance is all the more compelling. The basis for Provincial liability can also be found in the proposition that one who freely undertakes a task and performs it negligently is liable to persons who reasonably rely on this undertaking and are injured as a result[4].

The task of inspection - evaluation - regulation performed by the Province is designed to benefit the general public. The Province, in effect, believes that the benefits to the public of intervention into the prescription drug market place exceed the costs, including the cost of real human suffering that may result from discretionary drug substitution and mandatory drug selection. If the Province were not held liable for these untoward effects of its actions and statements, the regulations would be operated for the benefit of the many at the expense of a few, which is retrograde to progressive tort policies of risk spreading and loss sharing. Thus both legal doctrine and progressive tort policy would support Provincial liability for injuries resulting from discretionary drug substitution and mandatory drug selection.

Finally, it should be noted in passing that any negligent governmental approval of a drug product or discretionary substitution and mandatory drug selection does not exonerate the manufacturer from liability for its own negligence in designing, manufacturing, testing, labeling and providing directions for the use of one of its products.[3] Thus, a manufacturer whose negligent actions promote the notion of drug substitutability remains liable for the untoward consequences of that action even if they are given implicit or explicit approval by any level of government.

Footnotes

1. 3 R.S.O. 1980, at 601

2. Dutton v. Bognor Regis United Bldg Co. [1972] 1 Q.B. 373, [1971], All E.R. 462, Anns v. Merton London Borough Council [1978] A.C. 728 [1977] 2 All E.R. 492 (H.L.)

3. Hedley Bryne & Co. v. Heller & Partners [1964] A.C. 465, [1963] 2 All E.R. 575 (H.L.)

4. Baxter & Co. v. Jones [1903], 6 O.L.R. 360, 2 O.W.R. 573

5. Willis v. F.M.C. Mach & Chemicals Ltd. (1976) 68 D.L.R. (ed) 127 (P.E.I.S.C.).

APPENDIX H

Material Submitted to the Minister

1. A copy of each submission presented to the Commission.

2. A list of local Pharmacists' Associations in the Province of Ontario.

3. A timeline of those people and associations contacted by the Commission.

4. A 1981 publication by the Economic Council of Canada entitled: "Regulating the Price of Prescription Drugs in Canada: Compulsory Licensing, Product Selection and Government Reimbursement Programmes" by P.K. Gorecki.

5. A 1983 publication by Consumer and Corporate Affairs Canada entitled "Review of Section 41(4) of the Patent Act."

6. The 1984 United States Report on Third Party Prescription Programs compiled by the National Council of State Pharmaceutical Association Executives.

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